

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 July 2006 (27.07.2006)

PCT

(10) International Publication Number
WO 2006/077262 A1

(51) International Patent Classification:

A61M 5/158 (2006.01) A61M 5/142 (2006.01)

(21) International Application Number:

PCT/EP2006/050410

(22) International Filing Date: 24 January 2006 (24.01.2006)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

PA 2005 00115 24 January 2005 (24.01.2005) DK

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

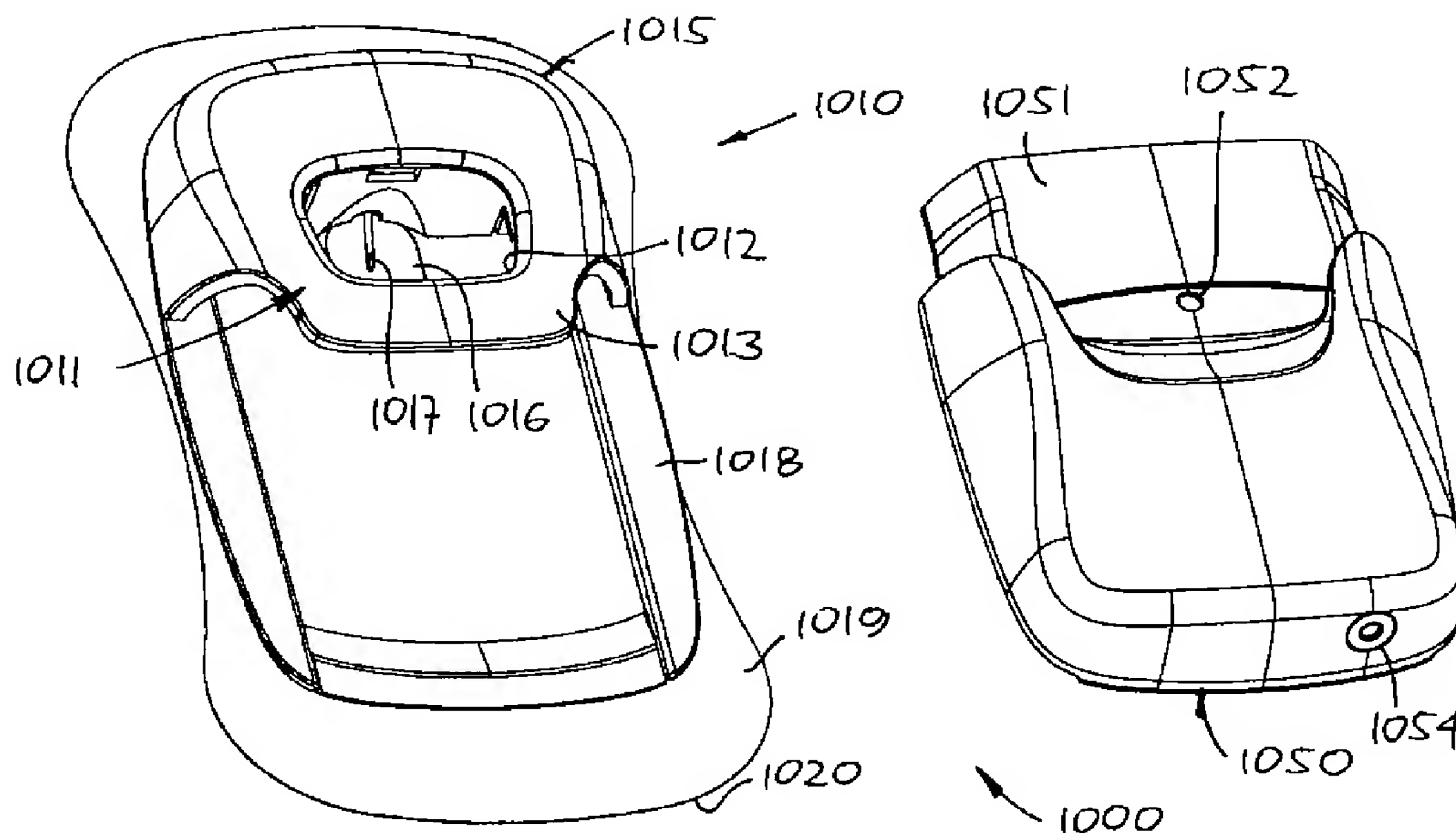
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MEDICAL DEVICE WITH PROTECTED TRANSCUTANEOUS DEVICE



(57) Abstract: A medical device is provided comprising a first a second units, the first unit comprising a housing with a skin-mountable surface, and a transcutaneous device having a distal portion adapted to be arranged through the skin of the subject in a situation of use in which the housing has been applied on a skin surface. The second unit is adapted to be releasably coupled to the first unit thereby, in a situation of use, substantially covering an introduction site of the transcutaneous device through the skin, whereby at least partial removal of the second unit from the first unit at least partially uncovers the introduction site. In this way the transcutaneous device can be protected during use, yet it allows the user to inspect the introduction site.

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MEDICAL DEVICE WITH PROTECTED TRANSCUTANEOUS DEVICE

The present invention generally relates to a device which is adapted for application to a skin surface of a subject and comprises a transcutaneous device. The transcutaneous device
5 may be in the form of a cannula or a sensor.

BACKGROUND OF THE INVENTION

In the disclosure of the present invention reference is mostly made to the treatment of diabe-
10 tes by injection or infusion of insulin, however, this is only an exemplary use of the present invention.

Portable drug delivery devices for delivering a drug to a patient are well known and generally comprise a reservoir adapted to contain a liquid drug and having an outlet in fluid communi-
15 cation with a hollow infusion needle, as well as expelling means for expelling a drug out of the reservoir and through the skin of the subject via the hollow needle. Such devices are often termed infusion pumps.

Basically, infusion pumps can be divided into two classes. The first class comprises infusion
20 pumps which are relatively expensive pumps intended for 3-4 years use, for which reason the initial cost for such a pump often is a barrier to this type of therapy. Although more complex than traditional syringes and pens, the pump offer the advantages of continuous infusion of insulin, precision in dosing and optionally programmable delivery profiles and user actuated bolus infusions in connections with meals.

Addressing the above problem, several attempts have been made to provide a second class of drug infusion devices that are low in cost and convenient to use. Some of these devices are intended to be partially or entirely disposable and may provide many of the advantages associated with an infusion pump without the attendant cost and inconveniencies, e.g. the
30 pump may be prefilled thus avoiding the need for filling or refilling a drug reservoir. Examples of this type of infusion devices are known from US patents 4,340,048 and 4,552,561 (based on osmotic pumps), US patent 5,858,001 (based on a piston pump), US patent 6,280,148 (based on a membrane pump), US patent 5,957,895 (based on a flow restrictor pump (also know as a bleeding hole pump)), US patent 5,527,288 (based on a gas generating pump), or
35 US patent 5,814,020 (based on a swellable gel) which all in the last decades have been pro-

posed for use in inexpensive, primarily disposable drug infusion devices, the cited documents being incorporated by reference. US patent 6,364,865 discloses a manually held infusion device allowing two vial-type containers to be connected and a pressure to be build up in one of the containers to thereby expel a drug contained in that container.

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The disposable pumps generally comprises a skin-contacting mounting surface adapted for application to the skin of a subject by adhesive means, and with the infusion needle arranged such that in a situation of use it projects from the mounting surface to thereby penetrate the skin of the subject, whereby the place where the needle penetrates the skin is covered while the appliance is in use. The infusion needle may be arranged to permanently project from the mounting surface such that the needle is inserted simultaneously with the application of the infusion pump, this as disclosed in US patents 2,605,765, 4,340,048 and in EP 1 177 802, or the needle may be supplied with the device in a retracted state, i.e. with the distal pointed end of the needle "hidden" inside the pump device, this allowing the user to place the pump device on the skin without the possibility of observing the needle, this as disclosed in US patents 5,858,001 and 5,814,020.

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As an alternative to a needle, a cannula in combination with an insertion needle which is withdrawn after insertion thereof may be used. Typically, the cannula is in the form of a relatively soft infusion cannula (e.g. a Teflon ® cannula) and a there through arranged removable insertion needle. This type of cannula and needle arrangement is well known from so-called infusion sets, such infusion sets typically being used to provide an infusion site in combination with (durable) infusion pumps. However, recently a disposable pump has been disclosed comprising an insertable soft cannula in combination with an insertion needle. More specifically, WO 03/090509 shows a skin mountable drug delivery device comprising an initially concealed soft cannula through which an insertion needle is arranged. With the device mounted on a skin surface the cannula can be released and inserted angled through the skin, the pointed distal end of the insertion needle projecting from the distal end of the cannula. When the cannula is fully inserted the insertion needle is withdrawn.

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When a needle or cannula or other transcutaneous device is introduced through the skin of a subject, problems may arise, e.g. incorrect insertion or infection, for which reason it is desirable to be able to inspect the site of insertion. On the other hand, it is also desirable to protect the transcutaneous device from influences from the outside, e.g. from water, dirt and mechanical influence. The latter is especially an issue for obliquely inserted soft cannulas as

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these normally projects a distance between a skin mountable device and the skin surface, this making the cannula very exposed.

DISCLOSURE OF THE INVENTION

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Having regard to the above-identified problems, it is an object of the present invention to provide a skin mountable medical device or system as well as components therefore, which allow such a device or system to be used in a convenient and cost-effective manner, yet allowing safe and reliable treatment of a medical condition.

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In the disclosure of the present invention, embodiments and aspects will be described which will address one or more of the above objects or which will address objects apparent from the below disclosure as well as from the description of exemplary embodiments.

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Thus, a medical device is provided comprising a first unit and a second unit, the first unit being a transcutaneous device unit comprising a housing adapted for application towards a skin surface of a subject, and a transcutaneous device having a distal portion adapted to be arranged through the skin of the subject in a situation of use in which the housing has been applied towards a skin surface of the subject. The second unit is adapted to be releasably coupled to the first unit, whereby, in a situation of use, it substantially covers an introduction site of the transcutaneous device through the skin. The other way round, at least partial removal of the second unit from the first unit will at least partially uncover the introduction site, this improving inspectability of the insertion site. In this way the transcutaneous device can be protected during use, yet it allows the user to inspect the introduction site. To allow a certain degree of inspection without having to fully or partly remove the second unit, one or both units may be provided with openings or transparent areas.

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The term "housing" merely denotes a supporting structure for supporting the different elements as described. The housing may be a traditional partially or fully closed structure, however, it may also be in the form of an open structure, e.g. a platform. The mounting surface may be provided by a sheet or foil member attached to the housing and comprising an adhesive lower surface, i.e. the mounting surface of the relatively rigid housing does not necessarily come in direct contact with a skin surface.

The distal portion of the transcutaneous device may be adapted to be arranged through the skin of the subject perpendicularly thereto or at an inclined angle relative to the skin surface. In the latter case, the distal portion may be inclined away from the first unit and towards the second unit when the first and second units are coupled to each other.

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The transcutaneous device may be permanently projecting from the first unit, and thus introduced through the skin simultaneously with the first unit being placed on a the skin surface, or it may be provided in an initially retracted position relative to the mounting surface, thereby allowing it to be moved to an extended (and thus inserted) position in which the distal portion projects relative to the mounting surface. Such a unit may comprise actuation means for moving the distal portion of the transcutaneous device between the initial and the extended position when the actuation means is actuated by a subject.

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In an exemplary embodiment the second unit is a process unit comprising a process assembly adapted to cooperate with the transcutaneous device. The transcutaneous device may be in the form of a transcutaneous sensor device, and the process assembly may comprise a processor adapted to transmit and/or process data acquired via the sensor device. Alternatively, the transcutaneous device may be in the form of a transcutaneous access device, and the process assembly may comprise a reservoir adapted to contain a fluid drug, an expelling assembly adapted for cooperation with the reservoir to expel fluid drug out of the reservoir and through the skin of the subject via the transcutaneous access device, and a processor for controlling the expelling assembly. In such a device the transcutaneous access device may be a flexible polymeric cannula.

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In a further embodiment a medical device unit adapted to be releasably coupled to a second unit is provided, the medical device unit being a transcutaneous device unit comprising a housing adapted for application towards a skin surface of a subject, the housing comprising a coupling portion adapted to engage the second unit, and a transcutaneous device having a distal portion adapted to be arranged through the skin of the subject, the distal portion projecting from the housing in the vicinity of the coupling portion.

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In a yet further embodiment a medical device is provided comprising a first unit and a second unit adapted to be releasably coupled to the first unit corresponding to a coupling zone, the first unit being a transcutaneous device unit comprising a housing adapted for application towards a skin surface of a subject, and a transcutaneous device having a distal portion

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adapted to be arranged through the skin of the subject, the distal portion projecting from the medical device corresponding to the coupling zone.

5 In a further embodiment a medical device is provided comprising a first unit and a second unit adapted to be releasably coupled to the first unit. The first unit is a transcutaneous device unit comprising a housing adapted for application towards a skin surface of a subject, and a transcutaneous device having a distal portion adapted to be arranged through the skin of the subject in a situation of use in which the housing has been applied towards a skin surface of the subject, the distal portion projecting from the housing thereby allowing, in a situation of use, inspection of an introduction site of the transcutaneous device through the skin
10 when the second unit is not coupled to the first unit, whereby the second unit when it is coupled to the first unit fully or partly covers the introduction site.

Also a method is provided comprising the steps of (a) providing a transcutaneous device unit
15 comprising a transcutaneous device and a mounting surface, the transcutaneous device having retracted position relative to the mounting surface, and an extended position in which a distal portion projects relative to the mounting surface, (b) providing a process unit comprising a process assembly adapted to cooperate with the transcutaneous device, (c) mounting the mounting surface to a skin surface of a subject, (d) inserting the transcutaneous device
20 into the subject by moving the transcutaneous device from the retracted position to the extended position, the configuration of the transcutaneous device unit allowing a subject to inspect the introduction site through the skin, and (e) assembling the transcutaneous device unit and the process unit to provide a functional communication between the process assembly and the inserted transcutaneous device, the process unit thereby fully or partly covering
25 ing and/or fully or partly preventing inspection of the introduction site.

As described above, a divided device may be provided with openings allowing the transcutaneous device to a certain degree. Thus, in an alternative embodiment, a medical device is provided comprising a housing comprising a mounting surface adapted for application towards a skin surface of a subject, and a transcutaneous device having a distal portion
30 adapted to be arranged through the skin of the subject in a situation of use in which the housing has been applied towards a skin surface of the subject. The distal portion is adapted to be arranged through the skin of the subject at an inclined angle relative to the mounting surface, with the cannula being directed towards a central portion of the medical device, the
35 medical device thereby, in a situation of use, substantially covering an introduction site of the

transcutaneous device through the skin, however, an opening is formed in the housing allowing the introduction site to be inspected by a user from the outside.

As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs include pharmaceuticals such as peptides, proteins, and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. In the description of the exemplary embodiments reference will be made to the use of insulin. Correspondingly, the term "subcutaneous" infusion is meant to encompass any method of transcutaneous delivery to a subject. Further, the term needle (when not otherwise specified) defines a piercing member adapted to penetrate the skin of a subject.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following the invention will be further described with reference to the drawings, wherein

figs. 1-3 shows in perspective views sequences of use for a first embodiment of a drug delivery device,

fig. 4 shows in a non-assembled state a needle unit and a reservoir unit for a further embodiment of a drug delivery device,

fig. 5 shows an exploded view of the needle unit of fig. 4,

fig. 6 shows a perspective view of the needle unit of fig. 4 in a first state,

fig. 7 shows a perspective view of the needle carrier of fig. 5,

fig. 8 shows a perspective view of the needle unit of fig. 4 in a second state,

fig. 9 shows a side view of the needle unit of fig. 4,

fig. 10 shows a further perspective view of the needle unit of fig. 4,

fig. 11 shows perspective view of the interior of the reservoir unit of fig. 4,

fig. 12 shows an exploded view of a further reservoir unit,

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figs. 13A and 13B show in a schematic representation a transcutaneous device in the form of a cannula and insertion needle combination,

fig. 14 shows a side view of a medical device mounted on a curved skin surface,

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fig. 15 shows medical device comprising a patch unit and an inserter unit,

fig. 16 shows an exploded view of the device of fig. 15,

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fig. 17 shows the device of fig. 16 from below,

figs. 18A-18F show different states of use of the device of fig. 15,

fig. 19 shows an exploded view of a patch unit comprising an inserter assembly,

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figs. 20A shows in an exploded view details of the inserter assembly of fig. 19,

fig. 20B shows the details of fig. 20A in an assembled state,

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figs. 21A-21D show different states of use of the device of fig. 19,

fig. 22 shows in an exploded view a schematic representation of a transcutaneous device unit,

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figs. 23A-23D show in different actuation states a mechanism for insertion of a cannula,

fig. 24 shows an exploded view of an inserter,

figs. 25A-25C show the relationship between the needle holder, the cannula holder, and the spring corresponding to the states shown in figs. 23A-23C,

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figs. 26A and 26B show in a non-assembled respectively assembled state a cannula unit and a reservoir unit for a further embodiment of a drug delivery device, and

5 fig. 27 shows an alternative configuration for the device of fig. 21A.

In the figures like structures are mainly identified by like reference numerals.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

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When in the following terms such as “upper” and “lower”, “right” and “left”, “horizontal” and “vertical” or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as there relative dimensions
15 are intended to serve illustrative purposes only.

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Firstly, with reference to figs. 1-3 an embodiment of a medical device for drug delivery will be described focusing primarily on the directly user-oriented features. The transcutaneous device unit 2 comprises a transcutaneous device in the form of a hollow infusion device, e.g. a
20 needle or soft cannula, and will thus in the following be termed a needle unit, however, the needle may be replaced with any desirable transcutaneous device suitable for delivery of a fluid drug or for sensing a body parameter.

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More specifically, fig. 1 shows a perspective view of medical device in the form of a modular skin-mountable drug delivery device 1 comprising a patch-like needle unit 2 (which may also be denoted a patch unit) and a reservoir unit 5. When supplied to the user each of the units are preferably enclosed in its own sealed package (not shown). The embodiment shown in fig. 1 comprises a patch unit provided with an insertable steel needle, however, the embodiment is exemplary of how to use a patch unit with an insertable transcutaneous device, e.g.
25 needle, cannula or sensor. In case an actual embodiment requires the patch unit to be mounted on the skin and the transcutaneous device inserted before a reservoir or other unit can be attached, it follows that the method of use would be adopted correspondingly.

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The needle unit comprises a flexible patch portion 10 with a lower adhesive mounting surface adapted for application to the skin of a user, and a housing portion 20 in which a hollow infu-
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sion needle (not shown) is arranged. The needle comprises a pointed distal end adapted to penetrate the skin of a user, and is adapted to be arranged in fluid communication with the reservoir unit. In the shown embodiment the pointed end of the needle is moveable between an initial position in which the pointed end is retracted relative to the mounting surface, and an extended position in which the pointed end projects relative to the mounting surface. Further, the needle is moveable between the extended position in which the pointed end projects relative to the mounting surface, and a retracted position in which the pointed end is retracted relative to the mounting surface. The needle unit further comprises user-gripable actuation means in the form of a first strip-member 21 for moving the pointed end of the needle between the initial and the second position when the actuation means is actuated, and user-gripable retraction in the form of a second strip-member 22 means for moving the pointed end of the needle between the extended and the retracted position when the retraction means is actuated. As can be seen, the second strip is initially covered by the first strip. The housing further comprises user-actuatable male coupling means 31 in the form of a pair of resiliently arranged hook members adapted to cooperate with corresponding female coupling means on the reservoir unit, this allowing the reservoir unit to be releasably secured to the needle unit in the situation of use. A flexible ridge formed support member 13 extends from the housing and is attached to the upper surface of the patch. In use a peripheral portion 12 of the patch extends from the assembled device as the reservoir unit covers only a portion 11 of the upper surface of the patch. The adhesive surface is supplied to the user with a peelable protective sheet.

The reservoir unit 5 comprises a pre-filled reservoir containing a liquid drug formulation (e.g. insulin) and an expelling assembly for expelling the drug from the reservoir through the needle in a situation of use. The reservoir unit has a generally flat lower surface adapted to be mounted onto the upper surface of the patch portion, and comprises a protruding portion 50 adapted to be received in a corresponding cavity of the housing portion 20 as well as female coupling means 51 adapted to engage the corresponding hook members 31 on the needle unit. The protruding portion provides the interface between the two units and comprises a pump outlet and contact means (not shown) allowing the pump to be started as the two units are assembled. The lower surface also comprises a window (not to be seen) allowing the user to visually control the contents of the reservoir before the two units are connected.

First step in the mounting procedure is to assemble the two units by simply sliding the reservoir unit into engagement with the needle unit (fig. 2). When the hook members properly en-

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gage the reservoir unit a “click” sound is heard (fig. 3) signalling to the user that the two units have been properly assembled. If desired, a visual or audible signal may also be generated. Thereafter the user removes the peelable sheet 14 to uncover the adhesive surface where after the device can be attached to a skin surface of the user, typically the abdomen. Infusion of drug is started by gripping and pulling away the actuation strip 21 as indicated by the arrow whereby the needle is inserted followed by automatic start of the infusion. The needle insertion mechanism may be supplied in a pre-stressed state and subsequently released by the actuation means or the needle insertion may be “energized” by the user. A “beep” signal confirms that the device is operating and drug is infused. The reservoir unit is preferably provided with signal means and detection means providing the user with an audible alarm signal in case of e.g. occlusion, pump failure or end of content.

After the device has been left in place for the recommended period of time for use of the needle unit (e.g. 48 hours) – or in case the reservoir runs empty or for other reasons - it is removed from the skin by gripping and pulling the retraction strip 22 which leads to retraction of the needle followed by automatic stop of drug infusion where after the strip which is attached to the adhesive patch is used to remove the device from the skin surface.

When the device has been removed the two units are disengaged by simultaneously depressing the two hook members 31 allowing the reservoir unit 5 to be pulled out of engagement with the needle unit 2 which can then be discarded. Thereafter the reservoir unit can be used again with fresh needle units until it has been emptied.

Fig. 4 shows a further embodiment of medical device 500 substantially corresponding to the embodiment of fig.1, the device comprising a transcutaneous device unit 502 and a process unit 505, More specifically, the transcutaneous device unit comprises a flexible patch portion (in the shown embodiment formed by a perforated sheet member 570) comprising an upper surface and a lower surface, the lower surface being adapted for application to the skin of a subject, a first housing 503 comprising a first coupling with two male coupling elements 511, and a transcutaneous device arranged in the housing (see below). Two supporting ridge members 561 extend from the first housing and are attached to the upper surface of the sheet member. The supports serve as attachment supports for the first housing, however, they may also serve to control the distance between the lower surface or the process unit and the patch. When the second unit is configured to accommodate at least partially the support members, e.g. in corresponding cut-out portions or grooves 504 (see fig. 12), the

supports may also serve to laterally stabilize the connection between the two units. The process unit comprises a second housing 501 with a lower surface and a second coupling arranged at a peripheral portion of the second housing, and a process assembly, e.g. a pump assembly as will be described below. In the shown embodiment the process unit has a generally flat rectangular shape with a cut-off end portion defining the interface with the transcutaneous device unit and also comprising the coupling in the form of two female coupling elements 506 arranged at each side of the end portion. Corresponding to figs. 1-3, the first and second couplings can be connected to each other with the upper surface of the patch facing towards the lower surface of the second housing. Due to the peripheral arrangement of the second coupling the flexible patch portion facing towards the lower surface of the second housing is free to move relative thereto, the degree of freedom being determined by the flexibility of the patch and supports if so provided and, of course, the surface to which the transcutaneous device unit is mounted.

In the shown embodiment the patch portion has the same general shape as the combined device albeit somewhat larger. In alternative embodiments the patch may comprise openings or cut-out portions. For example, an area between the two support legs may be cut out allowing the underlying skin to better breath.

Fig. 14 shows a side view of the assembled device 500 mounted on a curving skin surface 590. As appears, the flexible patch portion with its support members is allowed to follow the curvature of the skin, this creating a ventilation space between the process unit and the patch portion.

Fig. 5 shows an exploded perspective view of the needle unit comprising an upper housing portion 510, a needle carrier 520 and a thereto mounted infusion needle 530, an actuation member 540, a release member 550, a lower housing portion 560 and a sheet member 570 with a lower adhesive mounting surface 571. The actuation member comprises a user grippable portion 541 and a needle actuation portion 542, and the release member comprises a user grippable portion 551 and a needle retraction portion 552. In the assembled state as shown in fig. 6, the upper and lower housing portions form a housing 503 in which the needle and the needle carrier is mounted, the actuation and release members being operatable connected to the needle carrier with the user grippable portions arranged outside the housing. The sheet member further comprises an opening 572 arranged in register with a lower protrusion 565 provided around the exit aperture for the transcutaneous device, just as the sheet

is provided with a large number of small perforations to improve breathability through the sheet. The housing 503 is provided with user actuatable coupling means 511 allowing a reservoir unit to be attached to and released from the needle unit 505, the reservoir unit comprising corresponding mating coupling means 506 as well as a display 587. The display may indicate e.g. proper function of the unit, the amount of drug in the reservoir or different error conditions.

As seen is the user gripable portion 551 of the release member initially covered by a portion of the actuation member, this reducing the probability that the user erroneously uses the release member instead of the actuation member. Further, the actuation and release members (or portion thereof) may be colour coded to further assist the user to correctly use the device. For example, the actuation member may be green to indicate "start" whereas the release member may be red to indicate "stop".

Fig. 7 shows in perspective the needle carrier 520 with the needle 530 and the needle actuation portion 542 of the actuation member 540. The needle actuation portion comprises two legs 543 allowing it to slide relative to the housing, the legs being arranged through respective openings 563 in the housing. The needle carrier is adapted to be connected to a hinge member 562 of the lower housing portion to thereby allow the needle carrier and thereby the needle to pivot corresponding to a pivoting axis defined by a hinge. In the shown embodiment is the needle carrier in the form a bent sheet metal member, the carrier comprising an upper arm 521 and a lower arm 522 connected to each other by a hinge portion 523 allowing the lower arm to pivot relative to the upper arm and corresponding to the pivoting axis. The lower arm forms a tray in which the hollow infusion needle 530 is mounted (e.g. by welding or adhesive), the needle having a distal pointed portion 531 adapted to penetrate the skin of the subject, the distal portion extending generally perpendicular to the mounting surface of the needle unit, and a proximal portion 532 arranged substantially corresponding to the pivoting axis and adapted to engage a fluid supply. Thus, when a portion of the upper arm is mounted in the housing, the lower arm can pivot between a first retracted position in which the distal portion of the needle is retracted within the housing, and a second extended position in which the distal portion projects relative to the mounting surface. In the shown embodiment the needle carrier provides the drive means for moving the lower arm between the two positions. This may as in the present embodiment be provided by the elastic properties of the sheet material *per se* corresponding to the hinge portion, or alternatively an additional spring may be provided between the two arms to thereby urge them apart. To lock the lower part in an

energized, releasable first position, the upper arm is provided with a flexible release arm 526 comprising a catch 527 supporting and arresting the lower arm in its first downwardly biased position, as well as a release portion 528 engaging a ramp surface 544 of the needle actuation portion 542, the catch further comprising an inclined edge portion 529 adapted to engage the lower arm when the latter is moved from its extended to its retracted position as will be described in greater detail below.

To actuate the needle the user grips the flexible strip forming the user gripable portion 541 (which preferably comprises adhesive portions to hold it in its shown folded initial position) and pulls the needle actuation portion 542 out of the housing, the actuation member 540 thereby fully disengaging the housing. More specifically, when the ramp surface 544 is moved it forces the latch 527 away from the lower arm to thereby release it, after which the release portion 528 disengages the ramp allowing the two legs to be pulled out of the housing. As seen in fig. 8, when the actuation member is removed the user gripable portion 551 of the release member is exposed. As for the actuation member, the user gripable portion of the release member preferably comprises adhesive portions to hold it in its shown folded initial position.

In the shown embodiment the release member is in the form of a strip formed from a flexible material and having an inner and an outer end, the strip being threaded through an opening 512 in the housing, the strip thereby forming the user gripable portion 551 and the needle retraction portion 552, the inner end of the strip being attached to the housing and the outer end of the strip being attached to a peripheral portion of the sheet member 570 or, alternatively, a peripheral portion of the housing. In the projection shown in fig. 9 the release member is shown in its initial position, the retraction portion forming a loop 555 arranged below the lower arm of the needle carrier, this position allowing the lower arm to be moved to its actuated position and thereby the needle to its extended position.

When the user decides to remove the needle unit from the skin, the user grips the user gripable portion 551, lifts it away from the housing and pulls it upwardly whereby the loop shortens thereby forcing the lower arm upwardly, this position corresponding to an intermediate release state. By this action the lower arm engages the inclined edge portion 529 of the catch 527 thereby forcing it outwardly until it snaps back under the lower arm corresponding to the position shown in fig. 7. As the actuation member 540 has been removed from the needle unit, the needle carrier is irreversibly locked in its retracted position. When the user

further pulls in the release member, the peripheral portion of the sheet member to which the release member is attached will be lifted off the skin, whereby the needle unit with its attached reservoir unit can be removed from the skin, this as described above.

- 5 Advantageously, the actuation and release members may be formed and arranged to communicate with the reservoir unit (not shown). For example, one of the legs of the actuation member may in its initial position protrude through the housing to thereby engage a corresponding contact on the reservoir unit, this indicating to the reservoir unit that the needle unit has been attached, whereas removal of the actuation member will indicate that the needle
10 has been inserted and thus that drug infusion can be started. Correspondingly, actuation of the release member can be used to stop the pump.

In fig. 10 the side of the needle unit 502 which connects to the reservoir unit is shown. In addition to the two ridge members 561 and the user actuatable coupling means 511 the needle
15 unit comprises further structures which connects to and/or engages the reservoir unit to provide a functional interface with the reservoir unit. More specifically, the needle unit comprises a fluid inlet provided by the pointed proximal portion 532 of the needle projecting from the needle unit and adapted to engage a fluid outlet of the reservoir unit, an actuator 515 project-
ing from the needle unit and adapted to engage and actuate a fluid connector in the reservoir
20 unit (see below), and first and second contact actuators 548, 558 adapted to engage corresponding contacts on the reservoir unit. The first contact actuator is provided by the distal end of one of the legs 543 of the needle actuator projecting through an opening in the housing, and the second contact actuator is provided by a hinged portion of the housing connected to the needle retraction portion 552 of the release member 550. When the needle unit
25 is first connected to the reservoir unit both contact actuators will protrude from the housing and engage the corresponding contacts on the reservoir unit thereby indicating that that a needle unit has been connected. When the needle is actuated the first contact actuator will be withdrawn and thereby disengage the corresponding contact on the reservoir unit to start pump actuation. When the needle is retracted the second contact actuator will pivot and dis-
30 engage the corresponding contact on the reservoir unit to stop pump actuation.

Fig. 11 shows the reservoir unit with an upper portion of the housing removed. The reservoir unit comprises a reservoir 760 and an expelling assembly comprising a pump assembly 300 and control and actuation means 580, 581 therefore. The pump assembly comprises an out-
35 let 322 for connection to a transcutaneous access device (e.g. the needle 530) and an open-

ing 323 allowing an internal fluid connector to be actuated, see below. The reservoir 560 is in the form of prefilled, flexible and collapsible pouch comprising a needle-penetratable septum adapted to be arranged in fluid communication with the pump assembly, see below. The shown pump assembly is a mechanically actuated membrane pump, however, the reservoir and expelling means may be of any suitable configuration.

The control and actuation means comprises a pump actuating member in the form of a coil actuator 581 arranged to actuate a piston of the membrane pump, a PCB or flex-print to which are connected a microprocessor 583 for controlling, among other, the pump actuation, contacts 588, 589 cooperating with the contact actuators on the needle unit, signal generating means 585 for generating an audible and/or tactile signal, a display (not shown) and an energy source 586. The contacts are preferably protected by membranes which may be formed by flexible portions of the housing.

In fig. 12 an exploded view of the reservoir unit 505 of fig. 4 is shown, the unit comprising an upper housing member 507, a lower housing member 508 with a transparent area 509 and grooves 504 to receive the ridge members 561 extending from the needle unit, a flexible reservoir 760 with a rounded edge portion 762 on which a septum member 761 is mounted, a pump assembly 300 with actuator and a circuit board (not shown) arranged above the reservoir and comprising electronic components for controlling actuation of the pump. The upper and lower housing members comprise reservoir mounting means in the form of opposed upper and lower ridge portions 780 (the lower not seen) adapted to engage and mount the reservoir in the housing. Each ridge portion comprises a central cut-out portion 781 adapted to engage the septum member on its opposed surfaces when the housing members are assembled thereby locking the reservoir in place within the housing. The degree of locking will be determined by the pressure exerted on the septum member, the elastic properties of the septum member and the friction between the ridge and the septum member. On each side of the cut-out portion the ridge portions comprise a straight portion 782 which may aid in mounting the reservoir in the housing. The straight portions may engage the initially prefilled reservoir to help lock it in place, however, as the reservoir is emptied and flattens this grip may lessen. In contrast, the engagement with the septum is adapted to properly hold the reservoir in place as the reservoir is emptied. The straight portions may also be adapted to pinch and fully flatten the reservoir thus serving as an additional mounting means. Additional mounting means (not shown) may engage and grip the reservoir at other locations, e.g. along the welded edges 765.

In the above described embodiments, the transcutaneous device has been in the form of a unitary needle device (e.g. an infusion needle as shown or a needle sensor (not shown), however, the transcutaneous device may also be in the form of a cannula or a sensor in combination with an insertion needle which is withdrawn after insertion thereof. For example, the first needle portion may be in the form of a (relatively soft) infusion cannula (e.g. a Teflon[®] cannula) and a there through arranged removable insertion needle. This type of cannula needle arrangement is well known from so-called infusion sets, such infusion sets typically being used to provide an infusion site in combination with (durable) infusion pumps.

Thus, figs. 13A and 13B show in a schematic representation how a cannula and insertion needle combination can be arranged within a housing 601 of in a given medical device 600 (partly shown), e.g. an infusion device or an infusion set. More specifically, the medical device comprises a transcutaneous assembly 650 comprising a combination of a relatively soft cannula 651 (which e.g. may be of the soft "Teflon[®]" type) carried by a lower member 653 and a pointed insertion needle 661 (e.g. made from medical grade stainless steel) slidably arranged within the cannula and carried by an upper member 663, both members being mounted to allow axial displacement of the cannula respectively the insertion needle. The cannula comprises a proximal inlet (not shown) allowing it to be or to be arranged in fluid communication with a fluid source. The medical device further comprises a base plate 620 with an opening 621 for the cannula as well as a release member 622. The lower member comprises an elastomeric seal 652 through which the insertion needle is arranged. The cannula and the insertion needle may be straight or curved dependent upon how the two members are mounted in the device, e.g. arcuate corresponding to a pivoting axis or straight corresponding to linear movement as illustrated. The upper member comprises a coupling member 667 locking the members together in an initial position with distal end of the insertion needle extending from the distal opening of the cannula as shown in fig. 13A, and the base plate comprises coupling member 657 for locking the lower member in an extended position with distal end of the cannula extending through the opening in the base plate (see fig. 13B). Between the housing of the device and the upper member a first spring 668 is arranged biasing the upper member upwards. Correspondingly, the device also comprises a second spring 658 biasing the lower member upwardly. The medical device further comprises a gripping tab 676 and a pulling member 677 corresponding to the embodiment shown in fig. 1.

In a situation of use the assembly is moved downwardly, either manually or by a releasable insertion aid, e.g. a spring loaded member acting through an opening in the housing (not shown) whereby the cannula with the projecting insertion needle is inserted through the skin of a subject. In this position the lower member engages the coupling member 657 to thereby
5 lock the cannula in its extended position, just as the coupling member 667 is released by the release member 622 thereby allowing the upper member to return to its initial position by means of the first spring.

When the user intends to remove the delivery device from the skin surface, the user grips the
10 gripping portion of the tab and pulls it in a first direction substantially in parallel with the skin surface, by which action the flexible strip 677 releases the coupling member 657 from the lower member whereby the lower member and thereby the cannula is retracted by means of the second spring. When the cannula has been withdrawn from the skin, the user uses the now unfolded tab to pull off the entire delivery device from the skin surface, for example by
15 pulling the tab in a direction away from the skin surface.

With reference to figs. 15-18 a medical device 700 will be described comprising a cannula and an insertion needle (in the following also "needle" for short). The cannula may be in the form of what is traditionally referred to as a "soft catheter" or a "Teflon ® catheter". The device comprises two portions, a patch unit 710 comprising a housing mounted on a patch of flexible sheet material, and an inserter unit 720 removeably coupled to the patch housing. The inserter housing initially comprises the entire insertion mechanism including the cannula. When actuated the cannula becomes attached to the patch housing where after the inserter housing with the remaining inserter mechanism can be detached and discarded.

25 More specifically, the patch unit comprises a flexible sheet 721 with a lower adhesive surface and an opening 722 for the cannula, a patch housing with top 723 and base 724 portions, the base portion being attached to the upper surface of the sheet. The patch housing comprises an opening 725 for the cannula arranged just above the opening in the sheet, as well as a
30 coupling in the form of two flexible arms 726 allowing the inserter to be attached.

The inserter unit comprises an inserter housing with top 733 and base 734 portions, the base portion comprising two walls 735 with upper inclined edges serving as a ramp 736 for an inserter assembly 740. The inserter assembly comprises an inserter 750, a needle holder 760
35 comprising a needle 761 protruding there from, a cannula holder 770 with a cannula 771 pro-

truding there from, the cannula comprising a proximal needle penetratable septum, two springs 751 mounted on respective spring guides 752 on the inserter, and a release and retraction strip 780 (see fig. 18A). The strip comprises a proximal end projecting from the housing and a distal end attached to the needle holder, the strip forming a loop portion attached to the inserter. The inserter and the cannula holder are each provided with pairs of grooves 755, 775 allowing the inserter and the cannula to slide on the ramp. The inserter comprises an opening 753, an inclined ramp member 754 and a locking projection 757 adapted to engage a corresponding opening 737 in the housing. The needle holder comprises a flexible release arm 763 with an upwardly protruding catch 762, and the cannula holder comprises a pair of coupling elements 772 for engagement with the patch housing. In an initial assembled state (see fig. 17) the cannula holder is arranged in front of the inserter and the needle holder is arranged below the inserter with the needle positioned through the septum and within the cannula and projecting there from, and with the catch 762 protruding through the opening 753. As an example, the cannula may be a soft catheter with an OD of 0.7 mm and an ID of 0.4 mm and the needle may have an OD of 0.4 mm (G27). The inner surface of the inserter housing comprises a ramp 738 and a hold 739 adapted to engage the inserter assembly as described below. In a fully assembled initial state the inserter assembly is locked in place by the locking projections 757 engaging the opening 737 in the inserter housing, the springs being arranged in a compressed state between the inserter and the inserter housing. Upper guides 731 in the inserter housing secures that the inserter assembly can move only along the inclined ramp.

Next, with reference to figs. 18A-18F operation of a medical device of the above-outlined construction for insertion of a soft catheter will be described. The user first removes a protective sheet covering the adhesive surface of the patch and arranges the patch on a suitable skin portion of a subject, e.g. the abdomen. In the start position (see fig. 18A) the soft catheter holder with a soft catheter is placed in front of the inserter. The needle holder is connected to the inserter, which is loaded with springs (see fig. 15), all integrated in the inserter housing. The inserter needle is arranged inside the soft catheter with its pointed needle tip e.g. 2 mm in front of the soft catheter. Next the user pulls the strip which releases the inserter from the housing, this allowing the inserter assembly with soft catheter and needle holder to start move forwards pushed by the springs. As appears, by this action the strip is released from the needle holder. By the initial travel of the inserter assembly the inserter needle with soft catheter penetrates dermis 2-4 mm. During this movement the catch of the release arm on the needle-holder engages the ramp placed on the inserter-housing (see fig. 18B). The

ramp depresses the release arm in relation to its engagement with the inserter, and finally arrests the release arm as it engages the hold at the end of the ramp, this temporary halting movement of the needle holder. After needle movement has come to a halt, the inserter and the soft catheter holder continue forward movement driven by the springs, thereby moving the soft catheter ahead of the needle and into sub-cutis. The needle holder is stopped until the soft catheter tip is e.g. 1-5 mm in front of needle tip. During this movement the release arm on the needle holder is stopped by the hold in the housing, however, at the same time the flexible arm is engaged by the ramp member on the inserter. This ramp depresses the release arm until it is lifted free of the hold where after it again engages the inserter (see fig. 18C). After the needle holder has re-engaged the inserter, the needle now follows the soft catheter's movement through sub-cutis to a final position, and the needle can therefore act as guide for the soft catheter, with the tip of the needle e.g. 1-5 mm behind the tip of the soft catheter. When the cannula reaches its final fully extended position the soft catheter holder is positioned in the patch-housing where it is locked in place (see fig. 18D). As appears, the above-described actions all take place automatically driven by the springs and in a very short time, this providing minimum discomfort to the subject.

At this point the soft catheter has been placed at the desired place and what remains is for the user to withdraw the needle and remove the remaining inserter assembly and housing. In the shown embodiment the inserter is locked in place in its foremost position. The needle holder is released from the inserter and the needle is retracted by the user pulling the strip attached to the needle holder until the needle has been locked in its fully retracted position with the distal pointed end arranged within the inserter housing (see fig. 18E). In the shown embodiment the inserter serves to surround and protect the pointed end of the needle. Finally the user detaches the inserter housing from the patch unit which can then be disposed off (see fig. 18F). The cannula is now ready to be connected to a fluid source, e.g. a reservoir unit as shown in fig. 1 and of the same principal configuration as described with reference to figs. 11 and 12. Indeed, the interface of the pump assembly 300 will have to be modified in order to connect to the proximal septum of the soft catheter or cannula instead of a pointed needle end, i.e. the pump assembly will be provided with a pointed hollow needle establishing a fluid communication between the pump assembly and the inserted cannula.

With reference to figs. 15-18 an embodiment comprising a separate cannula inserter has been described, however, a corresponding mechanism may also be incorporated in a unitary patch unit. Such a design would indeed result in a larger patch housing, however, the user

would not have to detach and discard the inserter. For such a design the needle may be hollow and comprise a proximal end, with the distal end of the needle being in sealed fluid communication with the interior of the cannula when the needle has been arranged in its retracted position. By this arrangement a fluid communication can be provided between the proximal end of the needle and the cannula, this allowing the fluid communication to be established between the patch unit and the reservoir unit corresponding to the connection between the units in the figs. 5-12 embodiment. In this case a delivery device would supply drug to the cannula via the hollow needle.

With reference to figs. 19-21 a further integrated concept will be disclosed. The concept consists of an introducer needle surrounding a cannula, e.g. a soft catheter. The 1-2 mm cutis or derma is penetrated by the needle and only the soft catheter is inserted into sub-cutis. Once the soft catheter is fully inserted, the needle is retracted. Since the needle is placed on the outside of the soft catheter, the soft catheter can be made in a smaller diameter compared to a concept in which the needle is arranged inside the cannula and trauma in subcutis is thereby minimized, however, the larger diameter needle may cause larger trauma in the derma just as the cannula may be more susceptible to kinking and there may be less control when positioning the soft catheter in the subcutis. Also clotting during use may be more likely. These issues have to be considered when deciding on a specific concept and the specific design parameters for such a concept.

Turning to an exemplary embodiment, the medical device is in the form of a unitary patch unit 800 comprising a housing mounted on a patch of flexible sheet material, the inserter housing comprising the entire insertion mechanism including the cannula.

More specifically, the patch unit comprises a flexible sheet 821 with a lower adhesive surface and an opening 822 for the cannula (in this embodiment a flexible soft catheter), a patch housing with top 823 and base 824 portions (823' indicates a top portion shown upside down), with the base portion being attached to the upper surface of the sheet, wherein the top portion comprises a 45 degrees guide 825 for the cannula holder (see below). The patch housing comprises an opening for the cannula and needle arranged just above the opening in the sheet, as well as a coupling in the form of two flexible arms 826 allowing a delivery device to be attached. The base portion comprises two walls 835 with upper inclined edges serving as a ramp 836 for an inserter assembly 840. The inserter assembly comprises an inserter 850 with an attached needle 861 and a cannula holder 870 attached to a cannula

871 and adapted for moving the cannula relative to the inserter and thereby the needle (see
figs. 20A and 20B). The inserter is provided with pairs of grooves allowing the inserter to
slide on the ramp. The insertion mechanism further comprises a user-releasable spring (not
shown) for moving the inserter and a strip (not shown) for moving the cannula holder relative
5 to the inserter. As an example, the soft catheter may have an OD of 0.4 mm and an ID of 0.1
mm and the needle may have an OD of 0.7 mm and an ID 0.4 mm (G22).

To save space in the patch housing, the soft catheter introducing mechanism is placed per-
pendicular in respect of the direction of introduction. The soft catheter 871 is placed in a
10 groove 855 in the inserter that guides the soft catheter, the groove having a 90 degrees bend
to change the direction of the soft catheter during the introduction. As appears from figs. 20A
and 20B when the catheter holder 870 is moved across the inserter the soft catheter is ex-
tended in a perpendicular direction.

15 Next, with reference to figs. 21A-21D operation of a medical device of the above-outlined
construction for insertion of a soft catheter will be described. The user first removes a protec-
tive sheet covering the adhesive surface of the patch and arranges the patch on a suitable
skin portion of a subject, e.g. the abdomen. In the start position (see fig. 21A) the inserter is
arranged in its retracted position and the cannula holder is arranged in its initial position.
20 When the inserter is released (e.g. by pulling a strip to release a spring) the introducer nee-
dle with the soft catheter inside penetrates dermis e.g. 2-4 mm (see fig. 21B). By continuous
pulling the strip the user starts the introducing of the soft catheter into sub-cutis by pulling the
soft catheter holder across the inserter until the soft catheter is fully introduced (see fig. 21C).
After the soft catheter is fully introduced the user continues the pulling of the strip and pulls
25 the soft catheter holder further across the inserter, however, as the soft catheter holder has
reached the 45 degrees ramp, the inserter is forced backwards with the same speed as the
soft catheter is moved forward, the result is that the soft catheter stays in its final position and
the introducer needle on the inserter is removed and disappears into the patch housing (see
fig. 21D).

30 As the proximal end of the soft catheter is stationary, it may be provided with a pointed hol-
low needle which would allow a reservoir unit basically as shown in figs. 11 and 12 to be
connected thereto.

Fig. 22 shows in an upper exploded view a drawing of a schematic representation of a transcutaneous device unit (here a cannula unit) comprising a mechanism for inserting a soft cannula. The mechanism is similar to the mechanism described with reference to figs. 19-21. More specifically, the unit comprises a bottom part 910 onto which is mounted a chassis part 920 thereby creating an interior in which the different parts of the mechanism are arranged. In addition to the functional portions of the bottom and chassis part the mechanism comprises a needle holder 930 with a needle mount 931 to which a needle 932 is mounted, a cannula holder 940 comprising first and second gripping portions 941, 942 adapted to engage the needle holder, and a hollow cannula assembly comprising a soft, flexible cannula with a distal portion 951, an intermediate portion 952, and a proximal portion 953, the cannula assembly further comprising a tubular housing member 955 adapted to engage an opening 922 in the chassis portion, an elastomeric tubular member 956 in which the proximal end of the cannula is mounted, and a needle pierceable elastomeric septum, the tubular member and the septum being arranged in the housing member thereby providing a fluid inlet port for the hollow cannula. The mechanism further comprises a coil-formed torsion spring 960 comprising an actuator arm 961 with a curved distal end 962, the spring being arranged in a spring holder 970 comprising a catch 971 allowing the spring to be mounted in a pre-tensioned state. A release member 975 is provided comprising an outer end portion 976 adapted to engage e.g. a pump unit when the latter is mounted, and an inner end portion 977 adapted to engage and release the actuator arm from the spring holder. The bottom part comprises an inclined surface 911 with a guide 912 comprising a first guide groove 913 arranged corresponding to a longitudinal axis of the unit, and a second guide groove 914 arranged at an angle of 45 degrees relative to the first guide groove.

In the assembled state the cannula holder is mounted on the needle holder with the gripping portions 941, 942 arranged on each side of the needle mount 931, this allowing the cannula holder to slide along the length of the needle holder, the two holders thereby forming an inserter. In an initial state the distal portion of the cannula is positioned in the needle and the intermediate portion is positioned in a channel formed between the needle holder and the cannula holder, the cannula being mounted to the cannula holder by means of a flexible member on the first gripping portion.

In the assembled state the needle holder with the cannula holder mounted is arranged on the inclined surface and is allowed to slide up and down, with the guide grooves adapted to engage a guide member arranged on the lower surface of the cannula holder (not shown, see

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e.g. fig. 24). To control movement of the needle holder the needle mount comprises a guide portion 933 with two opposed grooves adapted to engage a corresponding guide member 921 arranged on an interior surface of the chassis part. As appears, in the shown schematic drawing the inclined surface 911 is shown without cut-out portions allowing the release member 975 and the spring holder 970 to be mounted (see below).

The bottom part 910 further comprises two opposed leg portions 918 each with a lobe 919, the lobes providing attachment points when the bottom part is mounted to a flexible sheet or foil member 901 comprising an adhesive lower mounting surface 904 allowing the transcutaneous unit to be mounted on a skin surface of a subject. The sheet member comprises a central opening 903 through which the needle and cannula is introduced, as well as a release liner 902. A cover portion 905 serves to close the interior thereby forming a substantially closed housing.

With reference to figs. 23A-23D the mechanism described with reference to fig. 22 is shown in a partly assembled state, the chassis part and the proximal portion of the cannula not being shown. The assembled embodiment differs slightly from the above-described embodiment, however, as the differences are small the same reference numerals are used.

The assembled embodiment primarily differs from the fig. 23 embodiment in that the inclined surface 911 has been replaced with a number of wall members, the upper surfaces of these wall members in combination providing an inclined "surface" on which the needle holder is arranged, this allowing the spring 960 and release member 975 to be shown functionally correctly arranged.

Fig. 23A shows the assembly in an initial state with the needle holder 930 in a first (or initial) retracted position with the needle correspondingly in its retracted position with the distal pointed end arranged within the housing. The cannula holder is positioned in a right-most position on the needle holder corresponding to its retracted position. The distal portion of the cannula is positioned in the needle with the distal end just within the distal end of the needle, and the intermediate portion is positioned in the channel formed between the needle holder and the cannula holder (see fig. 24), the cannula being gripped by a flexible arm formed as part of the first gripping member 941.

When a pump unit (not shown) is attached to the cannula unit the pump unit engages and pushes the outer end portion 976 of the release member 975, thereby releasing the spring actuator arm 961. The actuator then starts to turn clockwise (as seen in the figure) and engages a rear surface of the needle member pushing it forward to its extended position as seen in fig. 23B. During this movement the needle holder is guided linearly by engagement with the guide member 921 arranged on an interior surface of the chassis part, whereas the cannula correspondingly is guided linearly to its first extended position by engagement with the first guide groove 913. Thus, during this forward movement, the cannula holder does not move relative to the needle holder.

In this position the needle holder cannot be moved further forward, and as the spring actuator arm continues to turn clockwise it engages the guide member arranged on the lower surface of the cannula holder (not shown, see fig. 24) thereby starting to move the cannula holder to the left, sliding on the needle holder. At this position the guide member has reached the lower end of the first guide groove (see fig. 22) and is now moved into the second inclined guide groove where it is moved upwards along the guide groove, thereby being moved further to the left. As the cannula holder is attached to the needle holder, the needle holder is also moved upwards, however, it is guided linearly backwards due to the engagement with the guide member 921. When the cannula holder has reached the upper end of the second guide groove, it has reached its second extended position just as the needle holder has reached its second retracted position (the first and second retracted positions may be the same), just as the cannula holder has reached its second extended position.

As described above, the cannula has a distal portion initially arranged within the needle, an intermediate portion arranged in the channel formed between the cannula and needle holder, and a proximal portion serving as a flexible connection between the moving inserter and the fluid inlet port. As the cannula is attached to the cannula holder corresponding to the proximal end of the intermediate portion, movement to the left of the cannula holder will push the cannula through the channel, around the bend connecting the channel and the needle, and down into the needle. Thus as the cannula holder is moved from its first to its second extended position, the cannula is pushed out through the needle, whereas in the meantime the needle holder with the needle is retracted (see fig. 23C). In case the cannula and needle are extended respectively retracted at the same speed (this corresponding to the second guide groove being straight and arranged at an angle of 45 degrees relative to the first guide

groove) then the distal portion of the extended cannula will not move relative to the housing, whereas the needle will be retracted.

5 In order to allow the guide member of the cannula holder to properly enter the second guide groove, it may be desirable to connect the two guide grooves with a short groove portion, this providing that the cannula will be extended a little before the needle starts to retract, this as shown in fig. 23D. Correspondingly, by modifying the configuration of the second guide groove it is possible to retract the cannula a little from its most extended position. The latter may be desirable in order to free a distal cannula opening from any tissue plug formed during
10 insertion.

In fig. 24 is shown an exploded view of the inserter seen from below, i.e. the needle holder 930 and the cannula holder 940. In the figure the flexible arm 946 for holding the cannula in engagement with the first gripping member 941 can be seen, just as the guide member 945
15 arranged on the lower surface of the cannula holder can be seen. The needle holder is provided with a longitudinal wall portion 935 adapted for engagement with the spring actuator arm. Between the two holders a channel is formed in which the intermediate portion of the cannula initially is arranged.

20 In figs. 25A-25C are shown the relationship between the needle holder, the cannula holder, and the spring corresponding to the states shown in figs. 23A-23C. The partial assembly is rotated 180 degrees corresponding to the needle axis, and is thus seen from below.

In the initial position the actuator arm 961 is hold in its pre-stressed position in locking en-
25 gagement with the needle holder (see fig. 25A). When the spring is released the actuator arm start to turn counter clockwise (as seen in the figure) whereby it engages the wall portion 935 and start to move the needle holder 930 forwards to its extended position (see fig. 25B). As appears, the curved distal end 962 of the actuator arm allows the arm to slide on the wall. From this position the actuator arm continuous to turn counter clockwise and subsequently
30 engages the guide member 945 on the cannula holder 940 which is then moved to the right (as seen in the figure) to its second extended position and up, guided by the second guide groove, thereby moving the needle holder to its second retracted position (see fig. 25C). As appears, during the latter movement the guide member 945 slides on the actuator arm. As also appears, during movement of the cannula holder, the free proximal portion 953 of the

flexible cannula provides fluid communication between the remaining part of the cannula and the fluid port.

In the above described embodiment, a cannula is guided within a hollow needle, however, other arrangements may be used. For example, the needle may be part-circular (i.e. more than 180 degrees), this providing a smaller cross-sectional area during insertion. Alternatively, the needle and the cannula may be arranged side-by-side with corresponding gripping means provided there between providing that the cannula and needle are only allowed to move longitudinally relative to each other.

In traditional infusion sets a pointed needle is arranged inside a soft cannula, however, although the needle provides the cutting and columnar strength during insertion, the cannula is arranged unprotected against compressive forces in its longitudinal direction, such forces tending to collapse the cannula. Correspondingly, a typical infusion set cannula thus has a relatively thick wall with an outer diameter of 0.7 mm and an inner diameter of 0.4 mm. In contrast, by arranging the soft cannula inside the needle (which is typically made from medical grade stainless steel and thus very rigid), the properties of the needle material can be used to provide a much more thin-walled outer tubular structure. For example, a needle with an outer diameter of 0.5 mm and an inner diameter of 0.35 mm may be used, this providing less pain during insertion, just as a thinner soft cannula may be more comfortable to wear. A corresponding cannula will then have an outer diameter of close to 0.35 mm and an inner diameter typically in the 0.15-0.20 mm range. The cannula may be made from e.g. PTFE or FEP.

In the shown embodiment the cannula inserter mechanism is arranged in a cannula unit to be used in combination with a specific pump coupled directly thereto, however, the principles of the inserter mechanism may be used also in a conventional-type infusion set adapted to be connected to a drug delivery pump by a length of tubing. Further, instead of a flexible hollow cannula, a flexible sensor may be introduced. Also, instead of inserting the cannula at an inclined angle relative to a skin surface, a cannula may be inserted perpendicularly, i.e. inclined 90 degrees. Correspondingly, the mechanism may also be arranged to insert the cannula in a direction pointing away from the pump unit to which it is to be attached. In the shown embodiment the cannula is inclined 30 degrees relative to horizontal, however, a preferred range is 20-45 degrees. The less inclined the cannula is arranged, the longer the inserted length in the tissue may be, i.e. corresponding to the protruding length of a transcutaneous device below a plane defined by the mounting surface. For the shown angle of 30 de-

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grees a length of 8 mm is selected, this providing a vertical insertion of approximately 4 mm. For vertical insertion a length of 12 mm or less is preferred for a steel needle, whereas a length of 9 mm or less is preferred for a soft cannula. For a relatively "flat" insertion a length of 20 mm or less is preferred for a soft cannula, typically less than 17 mm.

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In fig. 26A is shown an embodiment of a medical device 1000 of the type shown in fig. 1, comprising a cannula unit 1010 and a thereto mountable pump (or reservoir) unit 1050, however, instead of a needle insertion mechanism as shown in fig. 7, a cannula inserter mechanism as described with reference to figs. 22-25 is used. In the shown embodiment the cannula unit comprises a housing 1015 with a shaft into which a portion 1051 of the pump unit is inserted. The shaft has a lid portion 1011 with an opening 1012, the free end of the lid forming a flexible latch member 1013 with a lower protrusion (not shown) adapted to engage a corresponding depression 1052 in the pump unit, whereby a snap-action coupling is provided when the pump unit is inserted into the shaft of the cannula unit. Also a vent opening 1054 can be seen. The housing 1015 is provided with a pair of opposed legs 1018 and is mounted on top of a flexible sheet member 1019 with a lower adhesive surface 1020 serving as a mounting surface, the sheet member comprising an opening 1016 for the cannula 1017.

As appears, from the housing of the cannula unit extends a cannula at an inclined angle, the cannula being arranged in such a way that its insertion site through a skin surface can be inspected (in the figure the full cannula can be seen), e.g. just after insertion. In the shown embodiment the opening in the lid provides improved inspectability of the insertion site. When the pump unit is connected to the cannula unit it fully covers and protects the cannula and the insertion site from influences from the outside, e.g. water, dirt and mechanical forces (see fig. 26B), however, as the pump unit is detachable connected to the cannula unit, it can be released (by lifting the latch member) and withdrawn fully or partly from the cannula unit, this allowing the insertion site to be inspected at any desired point of time. By this arrangement a drug delivery device is provided which has a transcutaneous device, e.g. a soft cannula as shown, which is very well protected during normal use, however, which by fully or partly detachment of the pump unit can be inspected as desired. Indeed, a given device may be formed in such a way that the insertion site can also be inspected, at least to a certain degree, during attachment of the pump, e.g. by corresponding openings or transparent areas, however, the attached pump provides a high degree of protection during use irrespective of the insertion site being fully or partly occluded for inspection during attachment of the pump.

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In the shown embodiment an inclined cannula is used, however, in an alternative embodiment a needle mechanism of the type shown in fig. 7 may be used if the point of insertion was moved closer to the coupling portion of the needle unit, this allowing also such a perpendicularly inserted to be inspected by detaching the pump unit.

Fig. 27 shows an alternative configuration for the device disclosed in fig. 21A. As the former embodiment the patch unit 1901 comprises a flexible sheet 1921 with a lower adhesive surface and an opening for the cannula, a patch housing 1923 attached to the upper surface of the sheet and comprising an opening for the cannula, as well as a coupling in the form of two flexible arms 1926 allowing a delivery device unit 1902 to be attached. However, in contrast to the former embodiment the orientation of the angled cannula 1971 has been reversed so that it points essentially in the opposite direction, i.e. towards the attached delivery device unit instead of away from the patch unit. Correspondingly, the opening in the flexible sheet is not peripherally but more centrally located (as indicated with dotted lines 1922 in fig. 21A). As appears, this arrangement allows the point of insertion of the cannula through the skin to be hidden and thus protected by the attached delivery device during normal operation of the assembled device, yet allows the cannula insertion site to be inspected by simply detaching and reattaching the delivery device unit. Further, as the modified inserter is moved towards the delivery device unit this movement may be used to connect the fluid inlet of the cannula with the fluid outlet from the delivery device unit, e.g. by means of a pointed needle connector and a needle penetratable septum arranged on either of the units. As appears, such a reversed arrangement may also be provided for a cannula inserter of the type disclosed with reference to figs. 15-18.

Indeed, the concept of a medical device comprising an angled insertable cannula which in its inserted position is covered by a detachable portion of the device can be used in combination with any type of cannula-needle arrangement, not only the embodiments disclosed above. The assembly may also be provided as a unitary device in which an opening may be formed allowing the insertion site to be inspected during use.

Although it is believed that the above-disclosed medical devices can be manufactured in a cost-effective manner, frequent changes of cannula or needle devices, e.g. infusion sets, is one of the cost drivers and poor convenience factors in CSII (continuous subcutaneous insulin infusion) treatment. It is today generally not recommended to wear an infusion set for

more than 2 days before changing it, but in practice pump users wear them for a longer time - on average 3.3 days. One of the limiting factors in wear time is that the risk of bacterial growth at the infusion site increases with longer wear times. The preservatives in insulin are anti-bacterial, but since they don't get in touch with the outside of the infusion needle they have no effect on this bacterial growth.

With a porous infusion needle or cannula having a pore size between the molecular size of the preservatives (typically small molecules like meta-cresol and phenol) and the molecular size of insulin (rather large molecules), some of the preservatives will move to the outside of needle where they can reduce bacterial growth and potentially increase the safe wear time of the infusion needle. For a polymeric cannula the entire tube or portions thereof thus can advantageously be made from a polymeric material allowing the preservatives to diffuse from the cannula and into the subcutis. A cannula may also be made from a fibrous material as used in micro tubes for dialysis. For a steel needle laser drilling of micro side openings would allow preservatives together with insulin to diffuse out in the subcutis along the needle (unless the side openings are made so small that they would be an effective barrier to the insulin molecules). The porous portion of the needle may be uniformly porous or it may be adapted to cause weeping at a non-uniform flow rate along the length of the porous portion. A porous portion may e.g. be located at the portion of the needle or cannula intended to cross the skin barrier. US 2004-0220536, which is hereby incorporated by reference, discloses a surgical needle with a porous distal portion from which a liquid injectate will weep or ooze multidirectionally under injection pressure while the porous distal portion of the needle is inserted into a body surface. More specifically, it is disclosed how a needle or cannula can be provided with pores from which a liquid will ooze. For example, the porous portion of the needle can be fabricated from any of a number of different "open cell" porous materials (i.e., materials in which the pores are interconnecting). For example, a distal portion can be fabricated from a porous sintered metal, such as forms a non-woven matrix of metal fibers selected from such metals as stainless steel, tantalum, elgiloy, nitinol, and the like, and suitable combinations of any two or more thereof. Generally, the metal fibers will have a diameter in the range from about 1.0 micrometer to about 25 micrometer. A non-woven matrix of metal fibers having these desired properties that can be used in manufacture of the porous distal portion of the invention needle is available from the Bekaeart Corporation (Marietta, Ga.), and is sold under the trademark, BEKIPOR RTM filter medium. A porous portion of the needle can also be fabricated from such porous materials as a porous polymer, such as a porous polyimide, polyethylene, polypropylene, polytetrafluoroethylene, and the like. Such po-

rous polymers are disclosed, for example, in US patent 5,913,856, which is hereby incorporated by reference in its entirety. Alternatively, a porous ceramic can be used, such as is known in the art for use in ceramic filters and separation membranes, or a porous metal (also known as an expanded metal) or carbon, such as is known in the art for use in filters or bone grafts. For example, Mott Corporation (Farmington, Conn.) manufactures porous metals for use in various types of filters. If the porous filter medium is flexible, a porous portion of a needle can be fabricated by wrapping the filter medium, which is available commercially as a flat sheet, one or more times around an axis while creating a hollow central core. The porous portion of the needle can then be fused in fluid-tight fashion (e.g. welded) to a non-porous hollow needle shaft using methods known in the art. To create a porous portion of the needle having decreasing impedance to fluid flow, a porous filter medium or metal mesh having an appropriate porosity gradient can be employed in fabrication of the porous portion. Alternatively, a porous portion can be created from a non-porous material (e.g., a metal) using a cutting laser and techniques known in the art to punch pores into the needle segment (i.e. by a process of laser etching). For example, the nonporous hollow shaft, porous portion, and point of a needle can be fabricated of metal in a single piece, for example, from a conventional hypotube. In this scenario, a metal-cutting laser is used to create a segment of the needle that has appropriate porosity, for example, a porosity gradient within a portion of the needle to equalize fluid impedance along the length of the porous portion of the needle.

The direct advantage of the above principle is a reduced bacterial growth at the infusion site compared with standard infusion needles. This increases user convenience, since an infusion set can be worn longer before it needs to be replaced – a replacement that can be painful especially for soft infusion needles where a large diameter steel needle is used to guide the soft infusion needle into the skin. Since infusion sets are typically rather expensive, increased wear time will furthermore be cost-attractive to pump users.

In the above description of the preferred embodiments, the different structures and means providing the described functionality for the different components have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

CLAIMS

1. A medical device comprising a first unit (1010) and a second unit (1050), the first unit being a transcutaneous device unit comprising:

5 - a housing (1015) comprising a mounting surface (1020) adapted for application towards a skin surface of a subject, and

- a transcutaneous device (1017) having a distal portion adapted to be arranged through the skin of the subject in a situation of use in which the housing has been applied towards a skin surface of the subject,

10 - the second unit being adapted to be releasably coupled to the first unit thereby, in a situation of use, substantially covering an introduction site of the transcutaneous device through the skin,

- wherein at least partial removal of the second unit from the first unit at least partially uncovers the introduction site.

15 2. A medical device as in claim 1, wherein the distal portion is adapted to be arranged through the skin of the subject at an inclined angle relative to the mounting surface.

20 3. A medical device as in claim 1, wherein the distal portion is inclined towards the second unit when the first and second units are coupled to each other.

4. A medical device as in any of claims 1-3, wherein the transcutaneous device has a retracted position relative to the mounting surface, and an extended position in which the distal portion projects relative to the mounting surface.

25 5. A medical device as in claim 4, wherein the transcutaneous device unit comprises actuation means (960) for moving the distal portion of the transcutaneous device between the retracted and the extended position when the actuation means is actuated by a subject.

30 6. A medical device as in any of claims 1-5, wherein the second unit is a process unit comprising a process assembly adapted to cooperate with the transcutaneous device.

35 7. A medical device as in claim 6, wherein the transcutaneous device is in the form of a transcutaneous sensor device, and the process assembly comprises a processor adapted to transmit and/or process data acquired via the sensor device.

8. A medical device as in claim 6, wherein the transcutaneous device is in the form of a transcutaneous access device, and the process assembly comprises a reservoir (760) adapted to contain a fluid drug, an expelling assembly (300, 580) adapted for cooperation with the reservoir to expel fluid drug out of the reservoir and through the skin of the subject via the transcutaneous access device, and a processor for controlling the expelling assembly.

9. A medical device as in claim 8, wherein the transcutaneous access device is a flexible polymeric cannula.

10. A medical device unit (1010) adapted to be releasably coupled to a second unit, the medical device unit being a transcutaneous device unit comprising:

- a housing adapted for application towards a skin surface of a subject, the housing comprising a coupling portion adapted to engage the second unit, and
- a transcutaneous device (1017) having a distal portion adapted to be arranged through the skin of the subject, the distal portion projecting from the housing in the vicinity of the coupling portion.

11. A medical device comprising a first unit (1010) and a second unit (1050) adapted to be releasably coupled to the first unit corresponding to a coupling zone, the first unit being a transcutaneous device unit comprising:

- a housing adapted for application towards a skin surface of a subject, and
- a transcutaneous device (1017) having a distal portion adapted to be arranged through the skin of the subject, the distal portion projecting from the medical device corresponding to the coupling zone.

12. A medical device comprising a first unit (1010) and a second unit (1050) adapted to be releasably coupled to the first unit, the first unit being a transcutaneous device unit comprising:

- a housing adapted for application towards a skin surface of a subject, and
- a transcutaneous device having a distal portion adapted to be arranged through the skin of the subject in a situation of use in which the housing has been applied towards a skin surface of the subject, the distal portion projecting from the housing thereby allowing, in a situation of use, inspection of an introduction site of the transcutaneous device through the skin when the second unit is not coupled to the first unit,

- whereby the second unit when it is coupled to the first unit fully or partly covers the introduction site.

13. A method comprising the steps of:

- 5 (a) providing a transcutaneous device unit (1010) comprising a transcutaneous device and a mounting surface, the transcutaneous device having retracted position relative to the mounting surface, and an extended position in which a distal portion projects relative to the mounting surface,
- 10 (b) providing a process unit (1050) comprising a process assembly adapted to cooperate with the transcutaneous device,
- (c) mounting the mounting surface to a skin surface of a subject,
- (d) inserting the transcutaneous device into the subject by moving the transcutaneous device from the retracted position to the extended position, the configuration of the transcutaneous device unit allowing a subject to inspect the introduction site through the skin,
- 15 (e) assembling the transcutaneous device unit and the process unit to provide a functional communication between the process assembly and the inserted transcutaneous device, the process unit thereby fully or partly covering the introduction site.

14. A medical device comprising:

- 20 - a housing comprising a mounting surface adapted for application towards a skin surface of a subject,
- a transcutaneous device having a distal portion adapted to be arranged through the skin of the subject in a situation of use in which the housing has been applied towards a skin surface of the subject, the distal portion being adapted to be arranged through the skin of the subject at an inclined angle relative to the mounting surface, the cannula being directed towards a central portion of medical device, the medical device thereby, in a situation of use, substantially covering an introduction site of the transcutaneous device through the skin, and
- 25 - an opening formed in the housing allowing the introduction site to be inspected.

Fig. 1

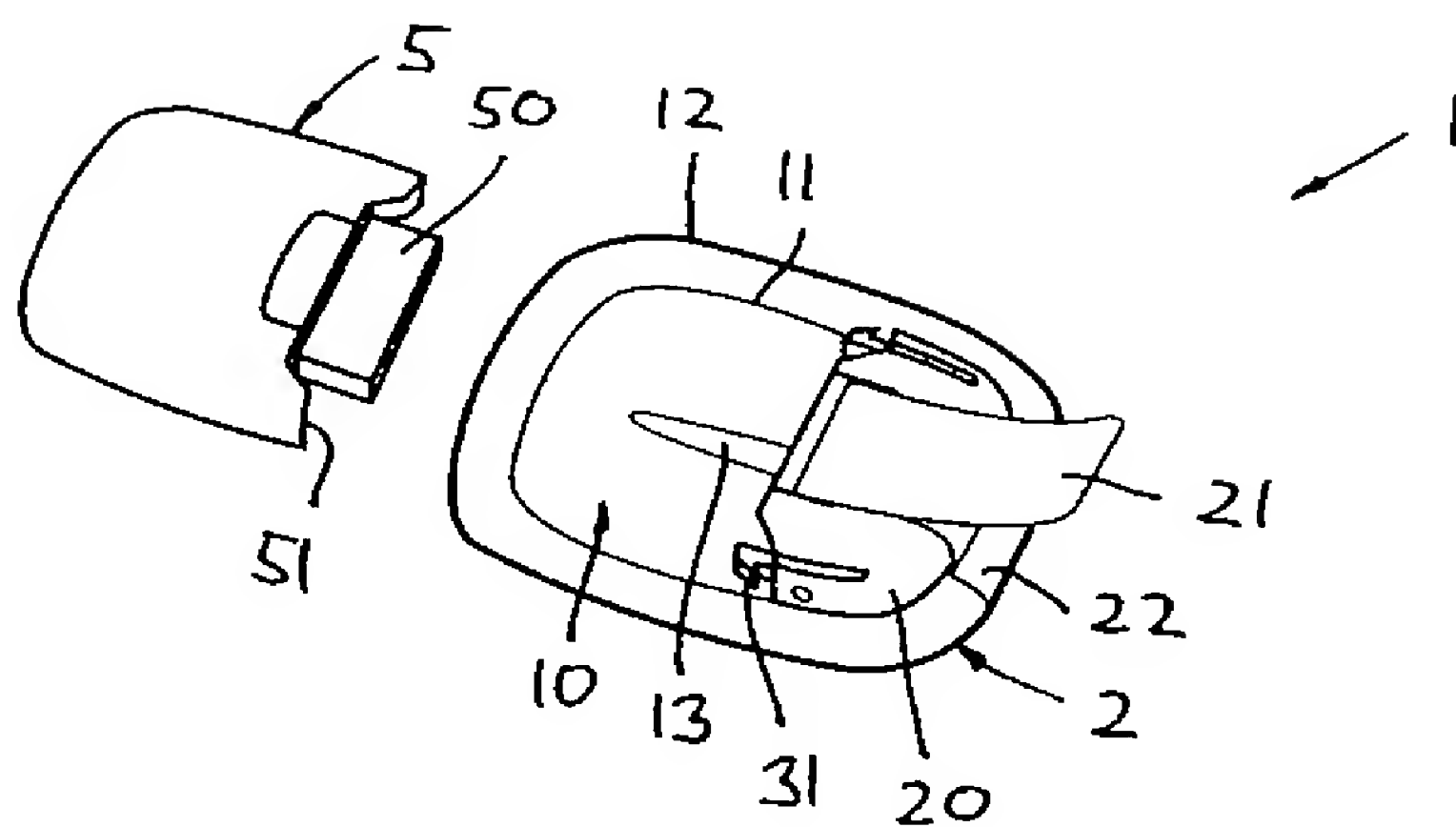


Fig. 2

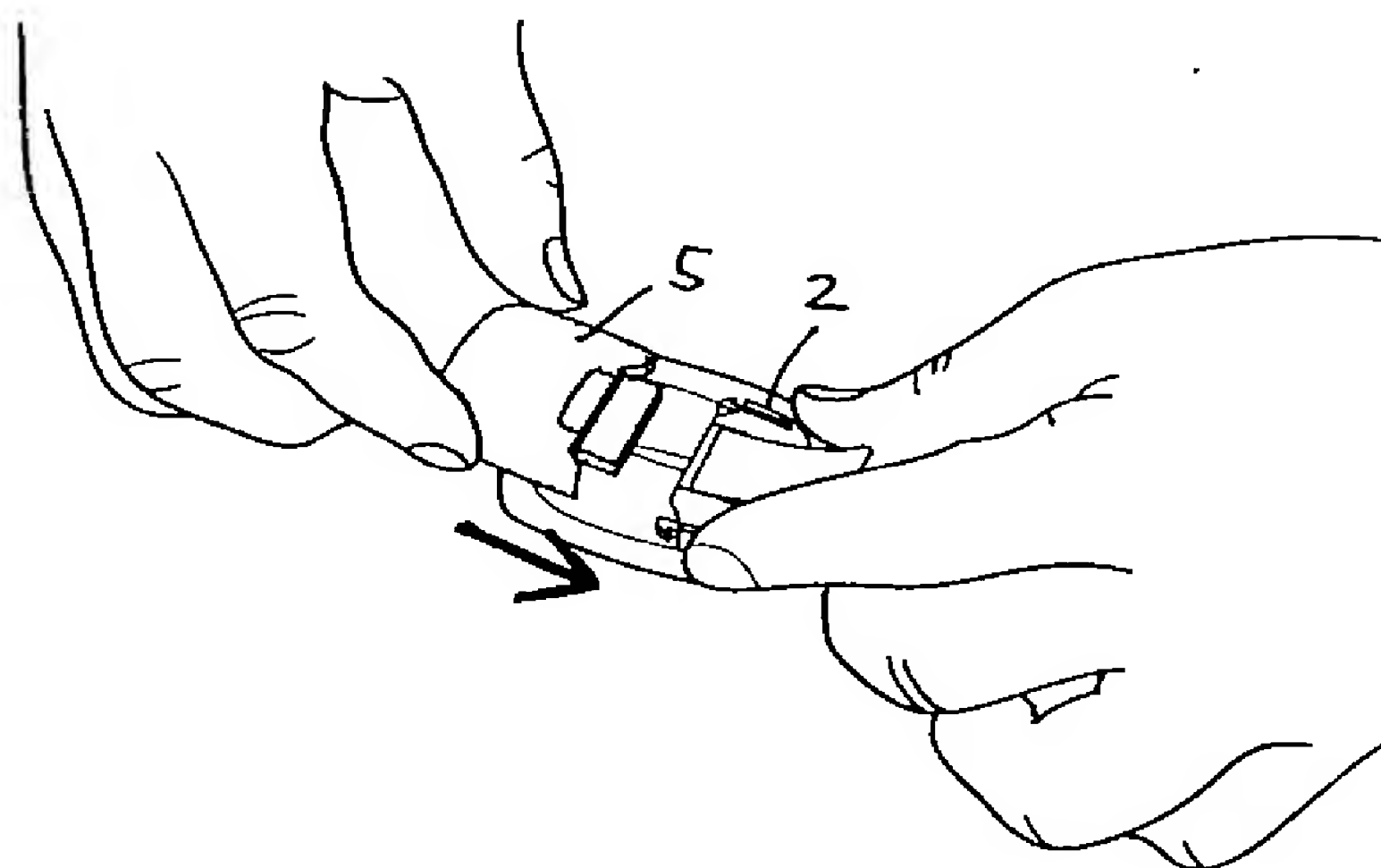


Fig. 3

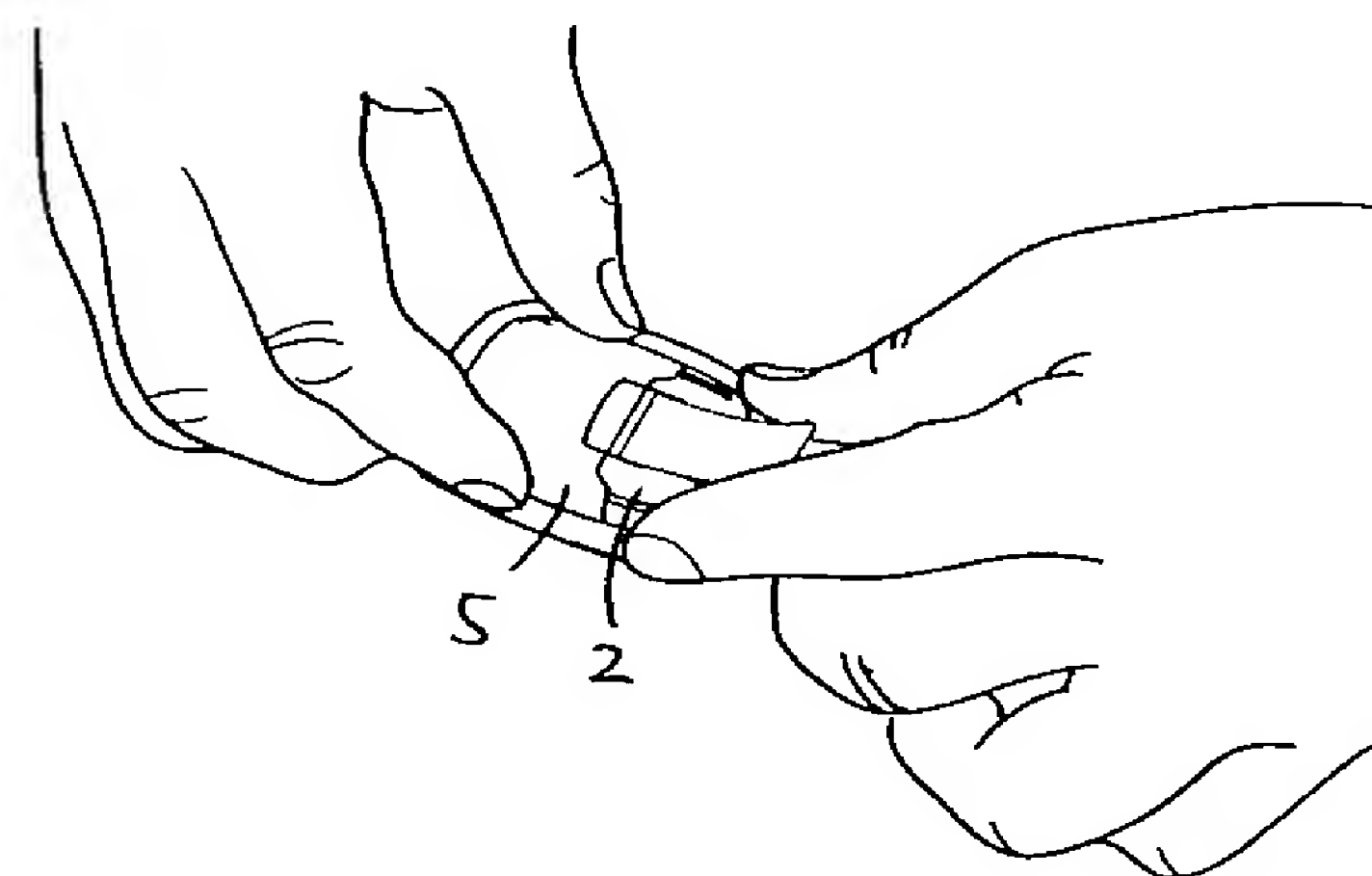


Fig. 4.

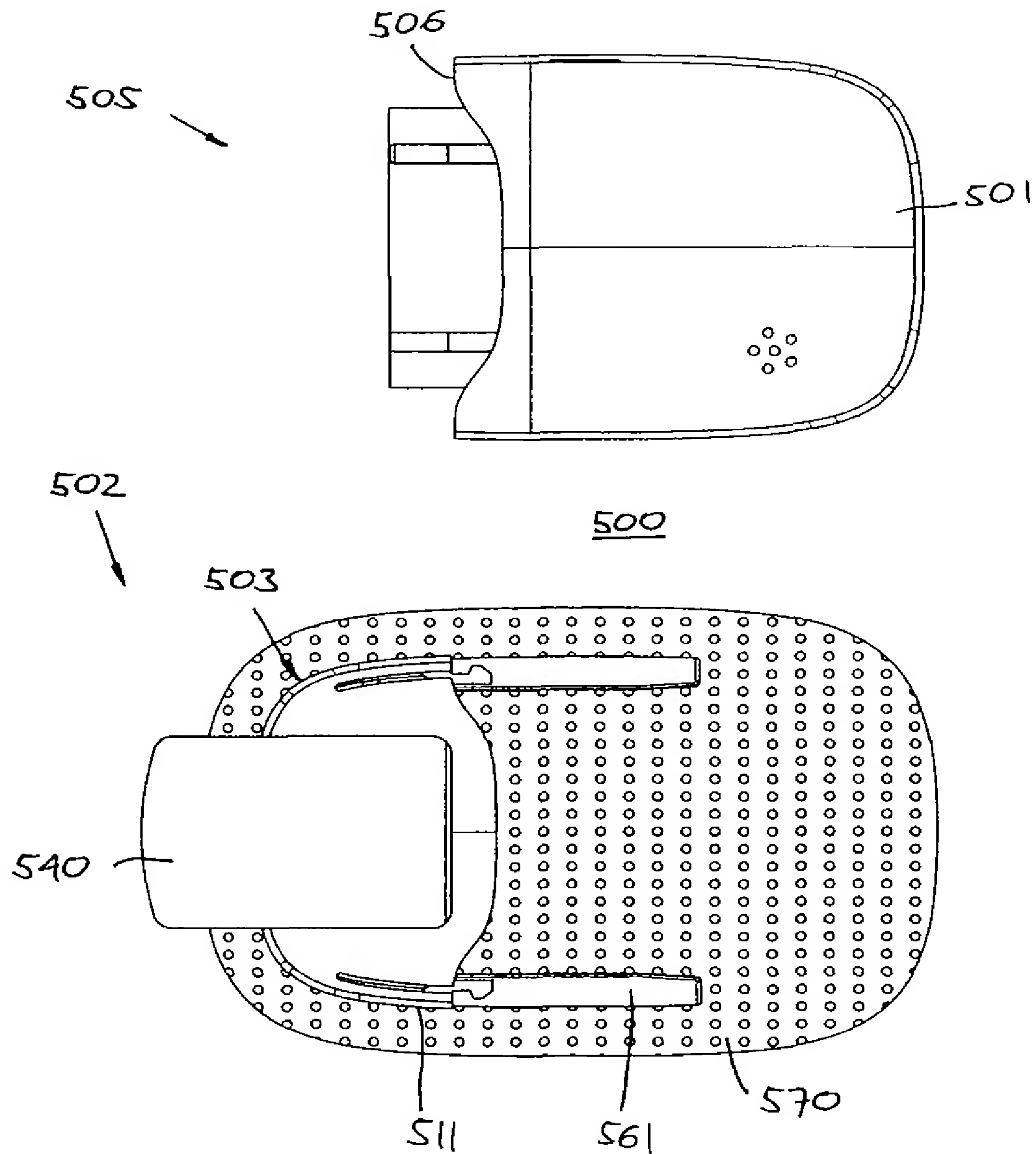


Fig. 5

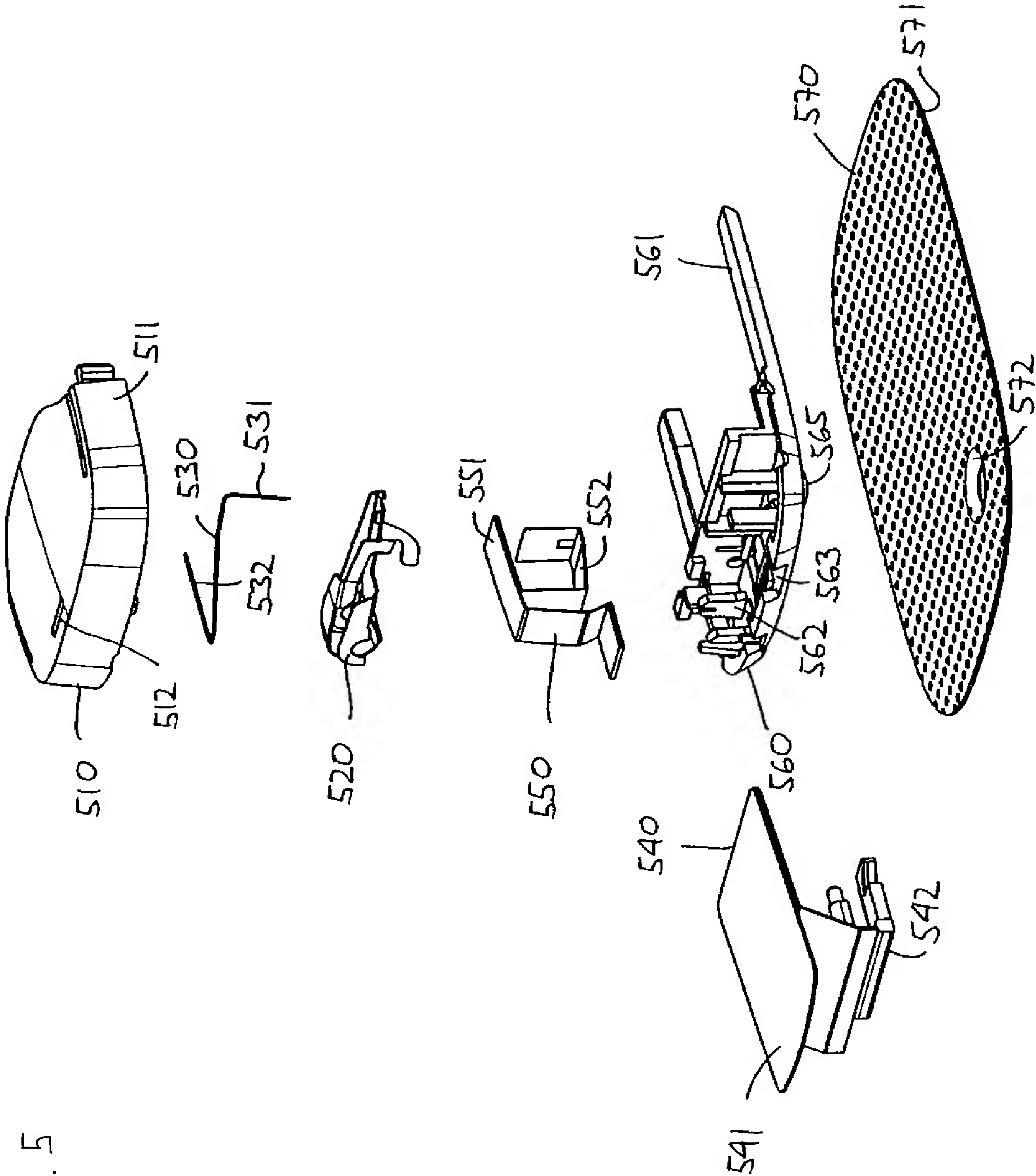


Fig. 6

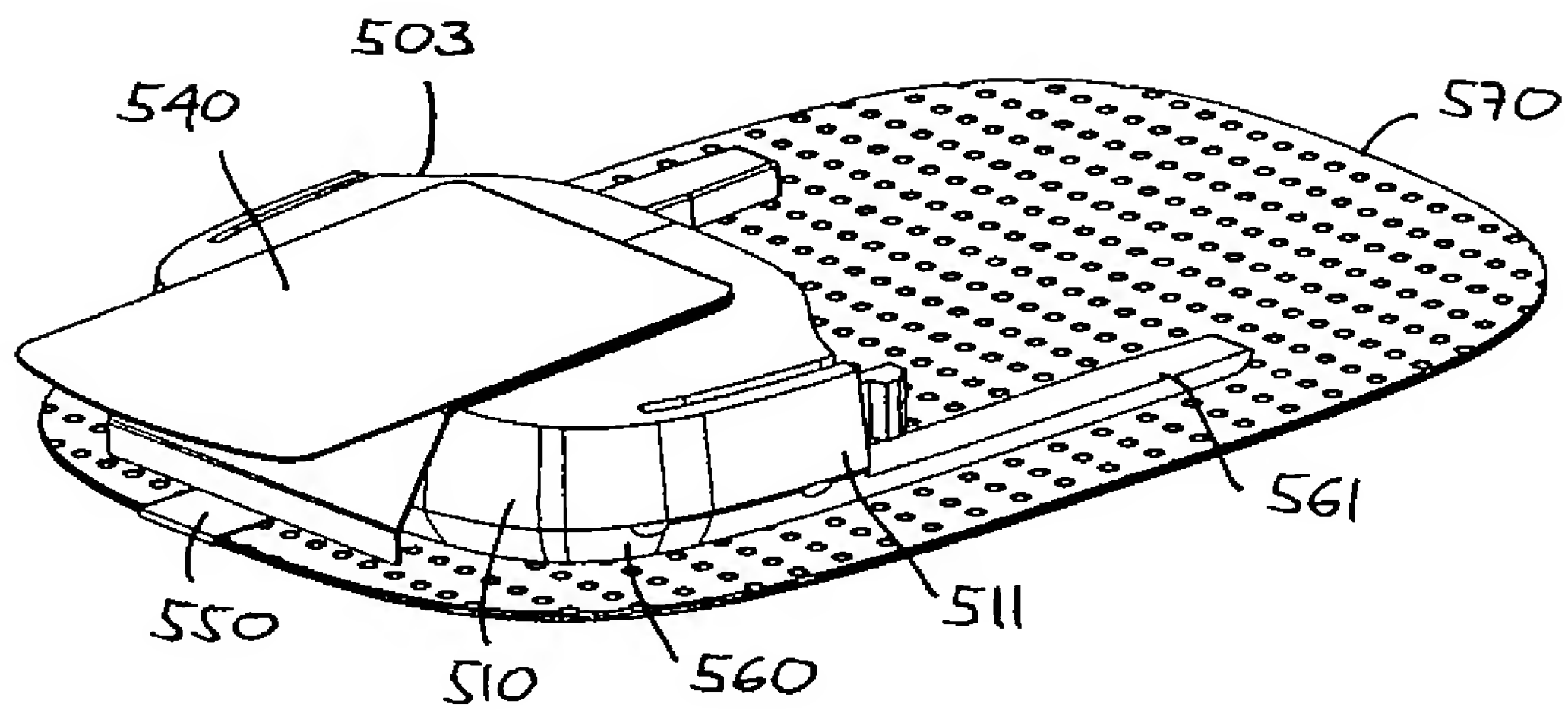


Fig. 7

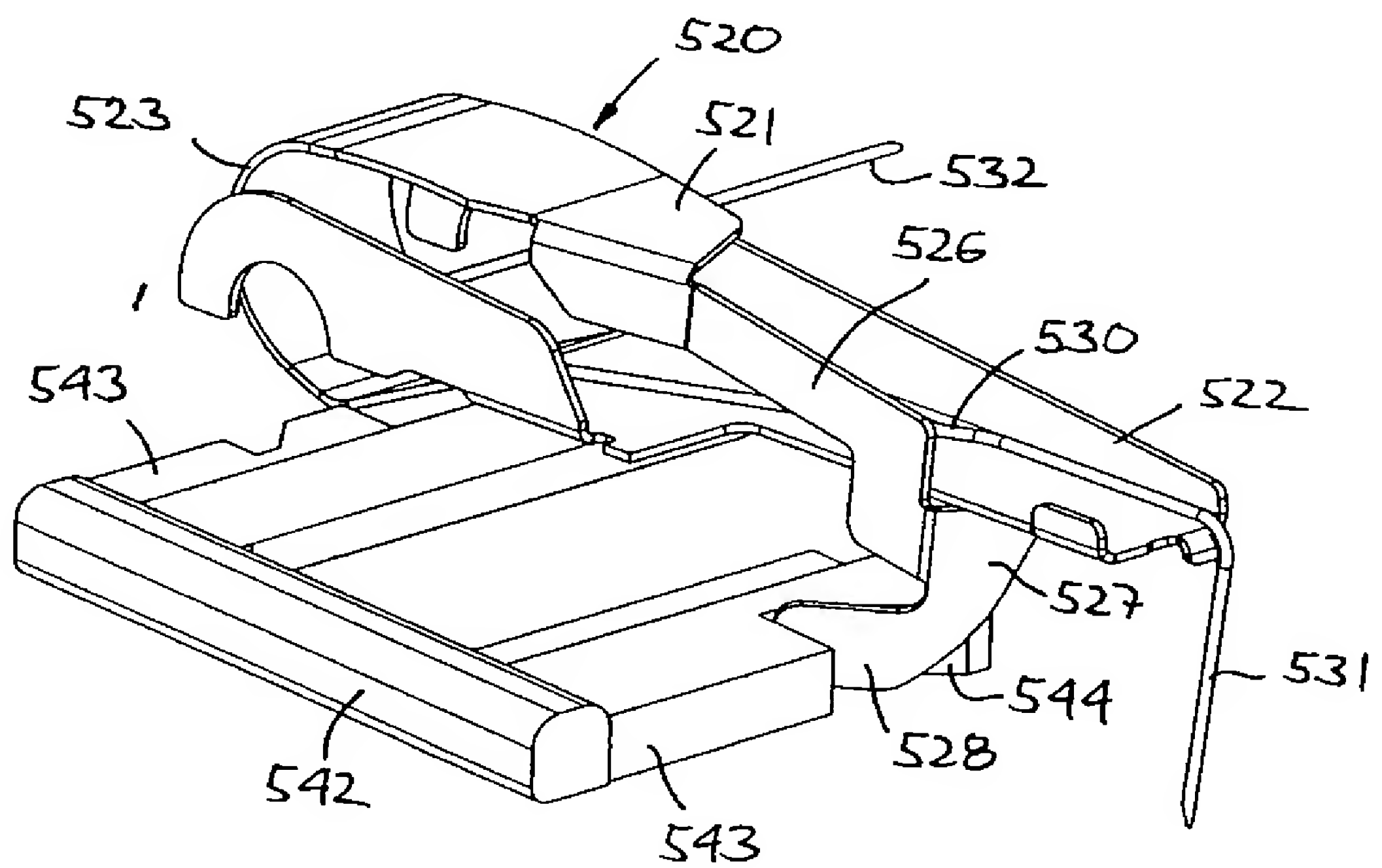


Fig. 8

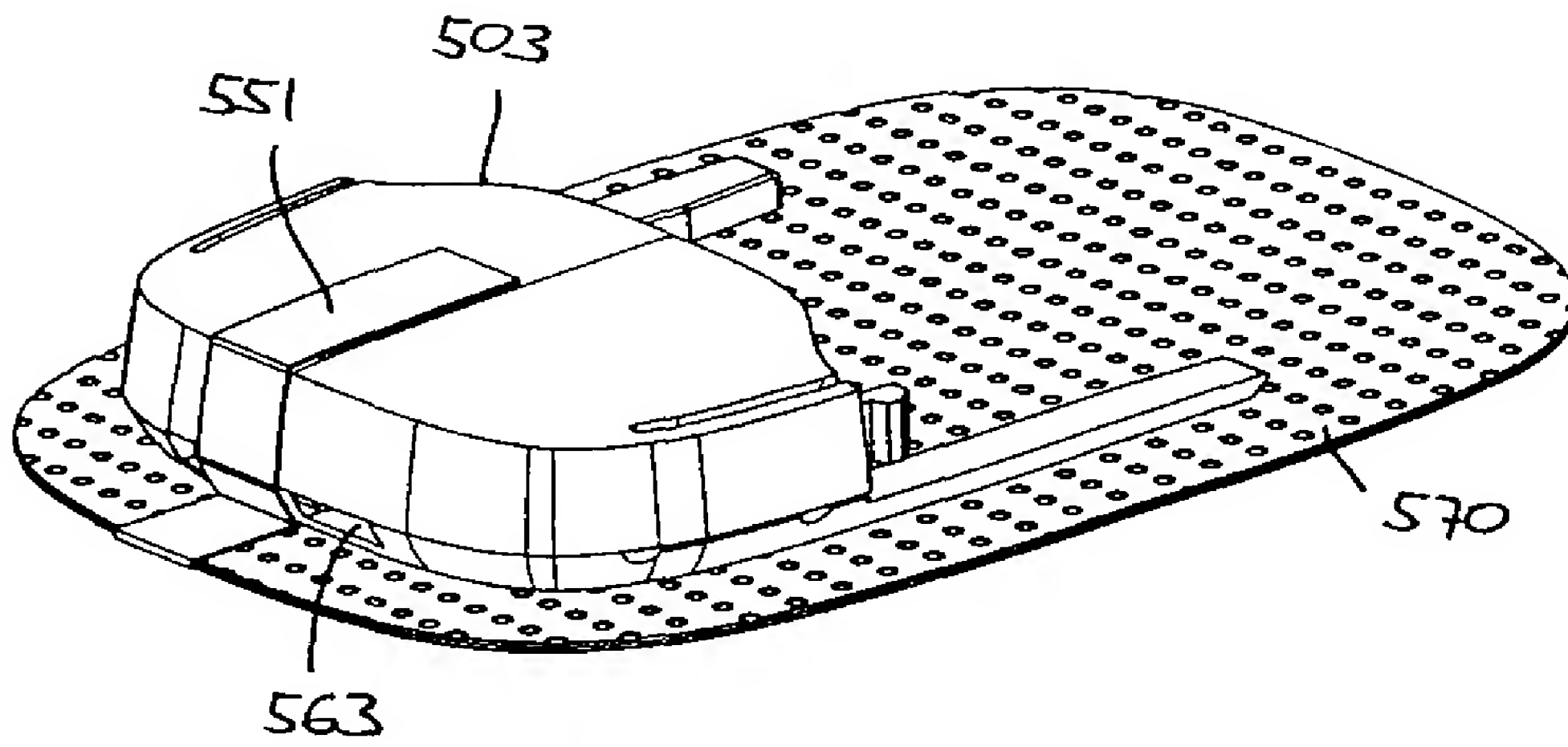


Fig. 9

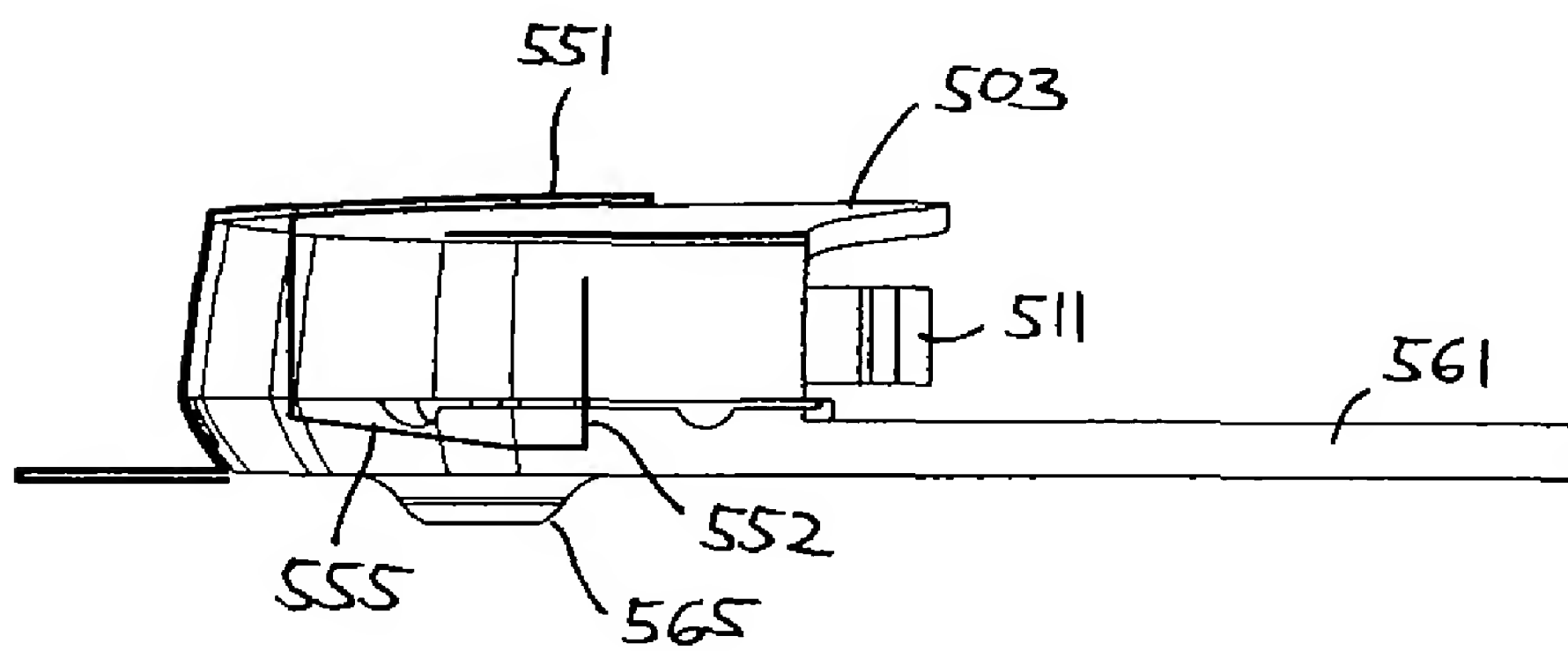


Fig. 10

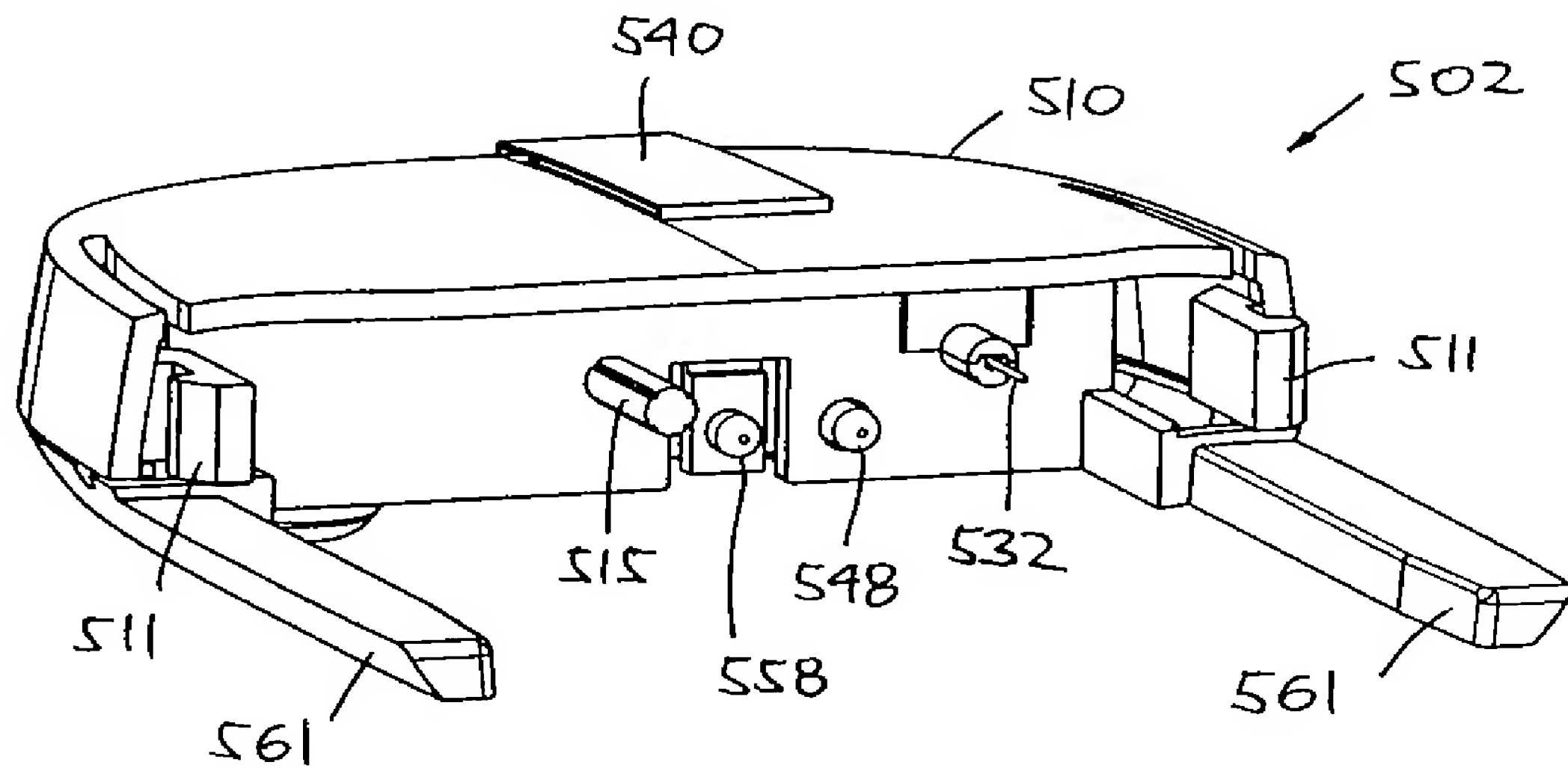


Fig. 11

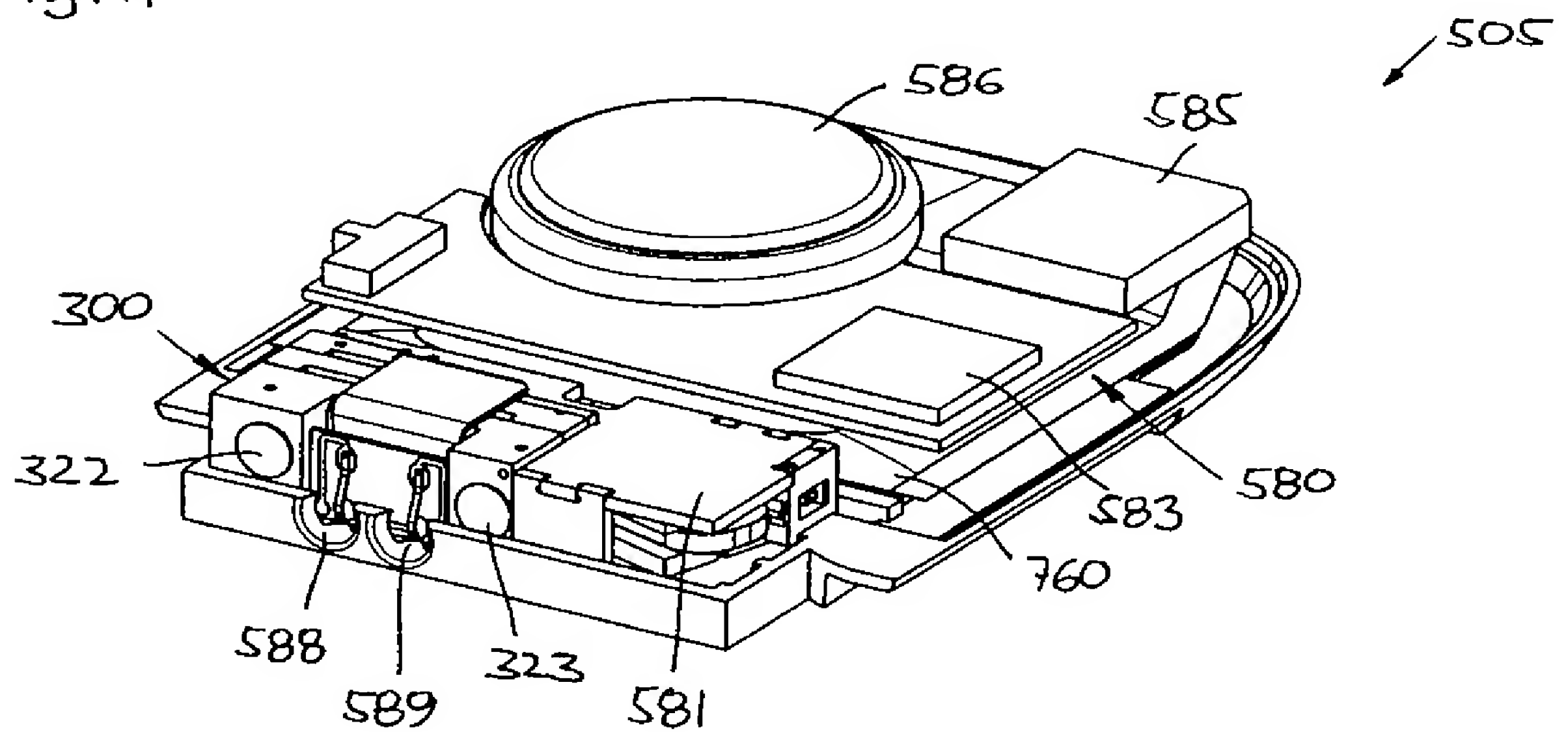


Fig. 12

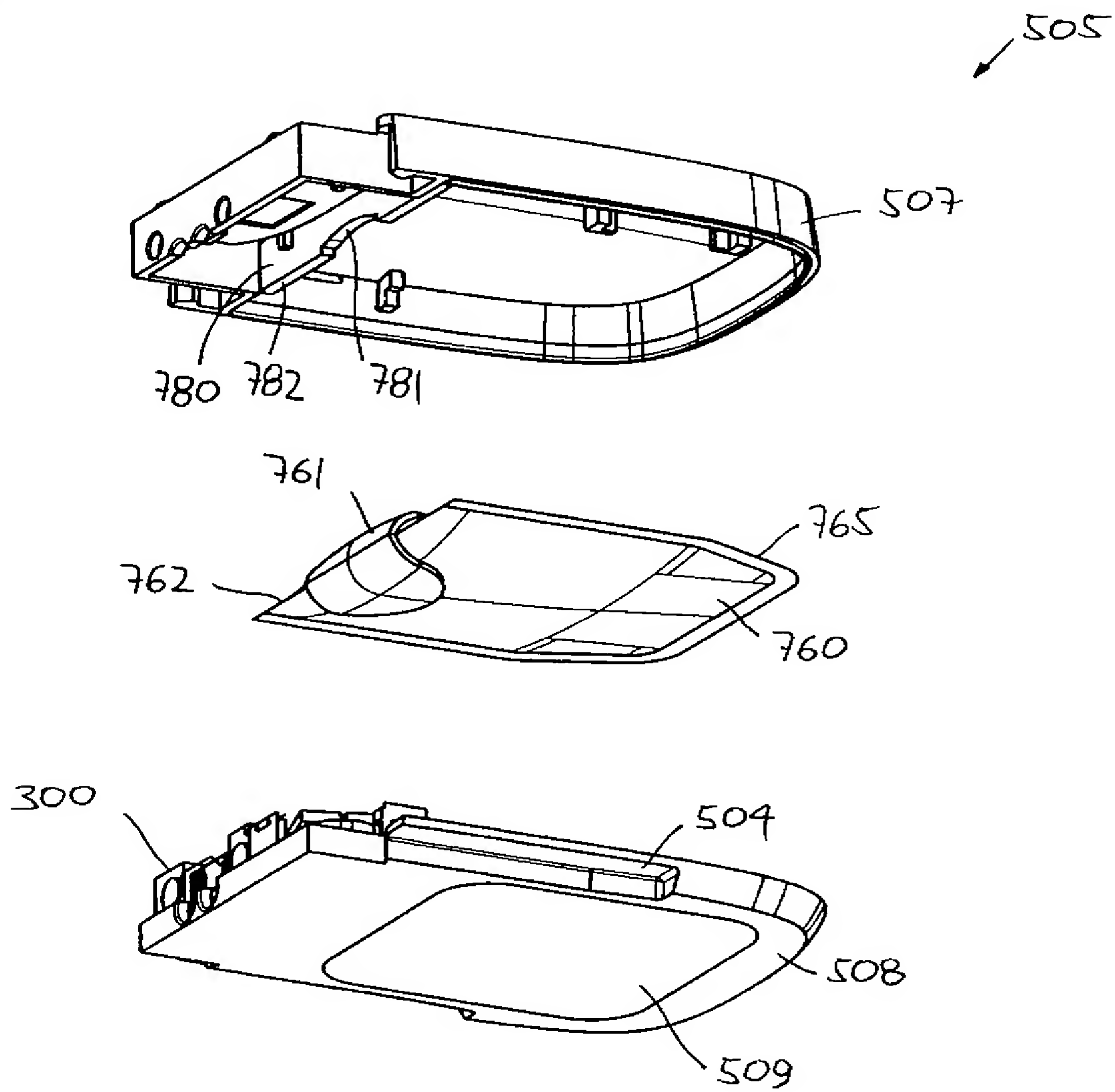


Fig. 13A

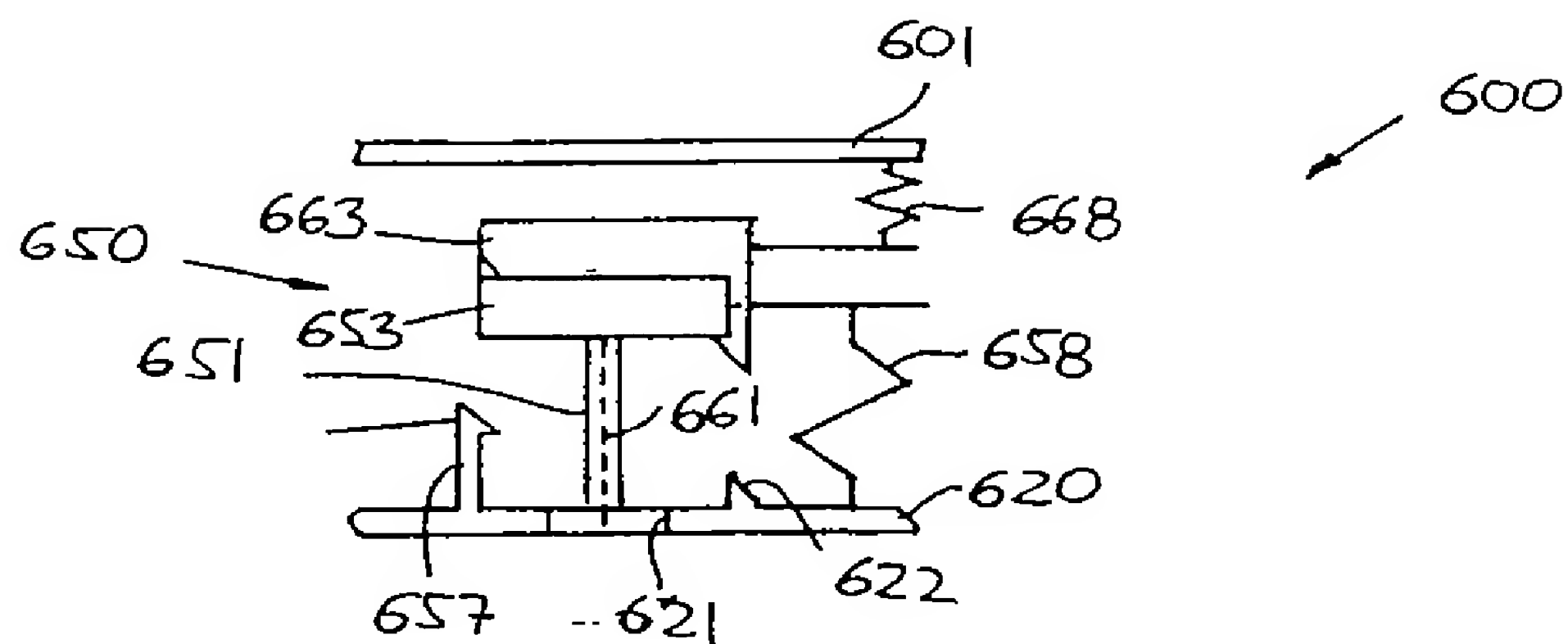


Fig. 13B

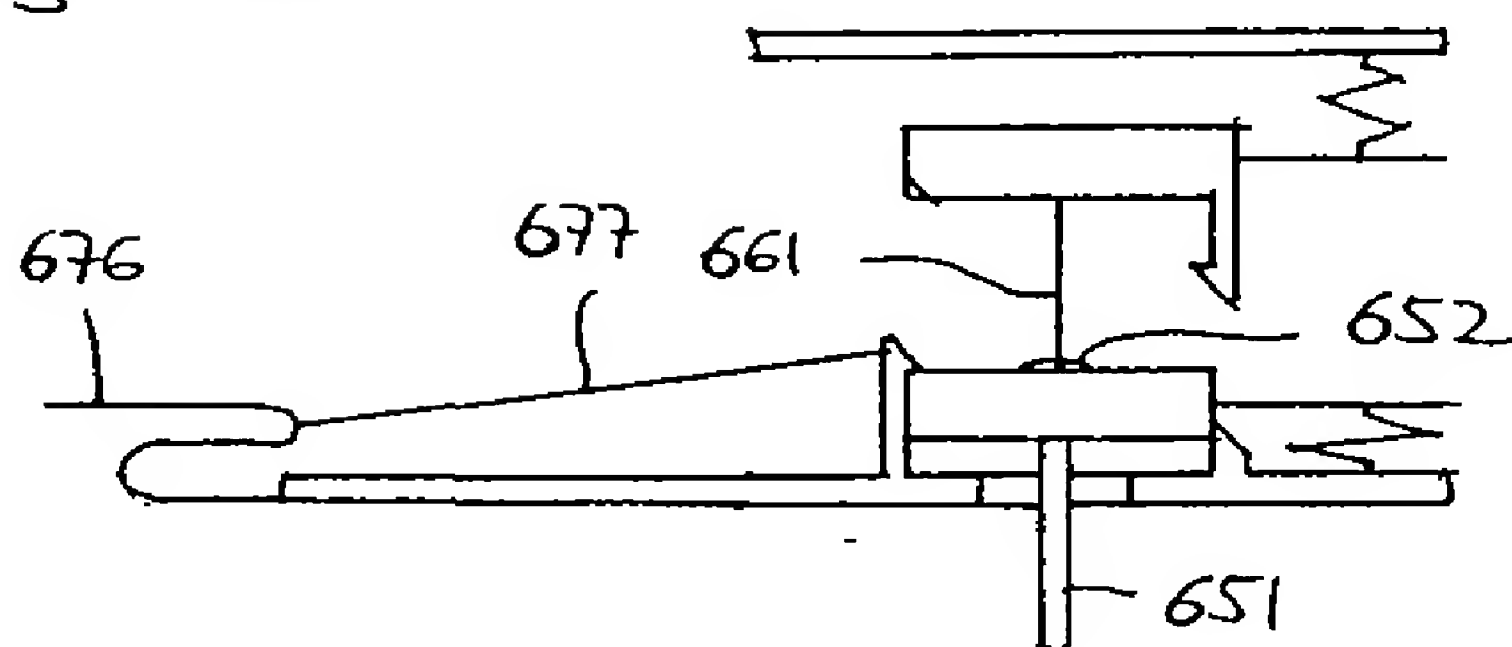


Fig. 14

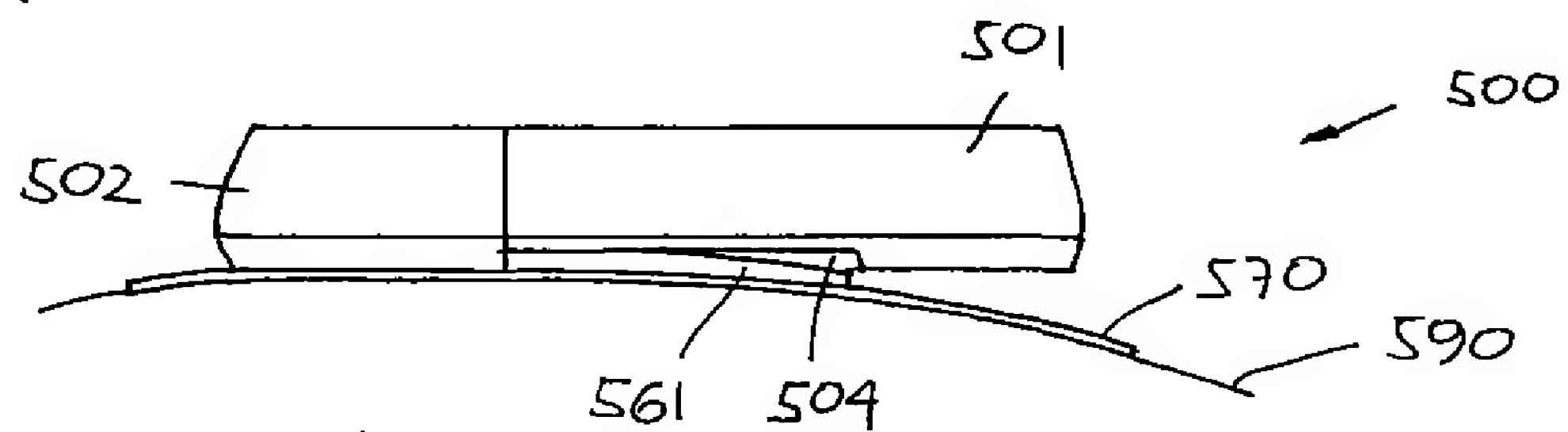


Fig. 15

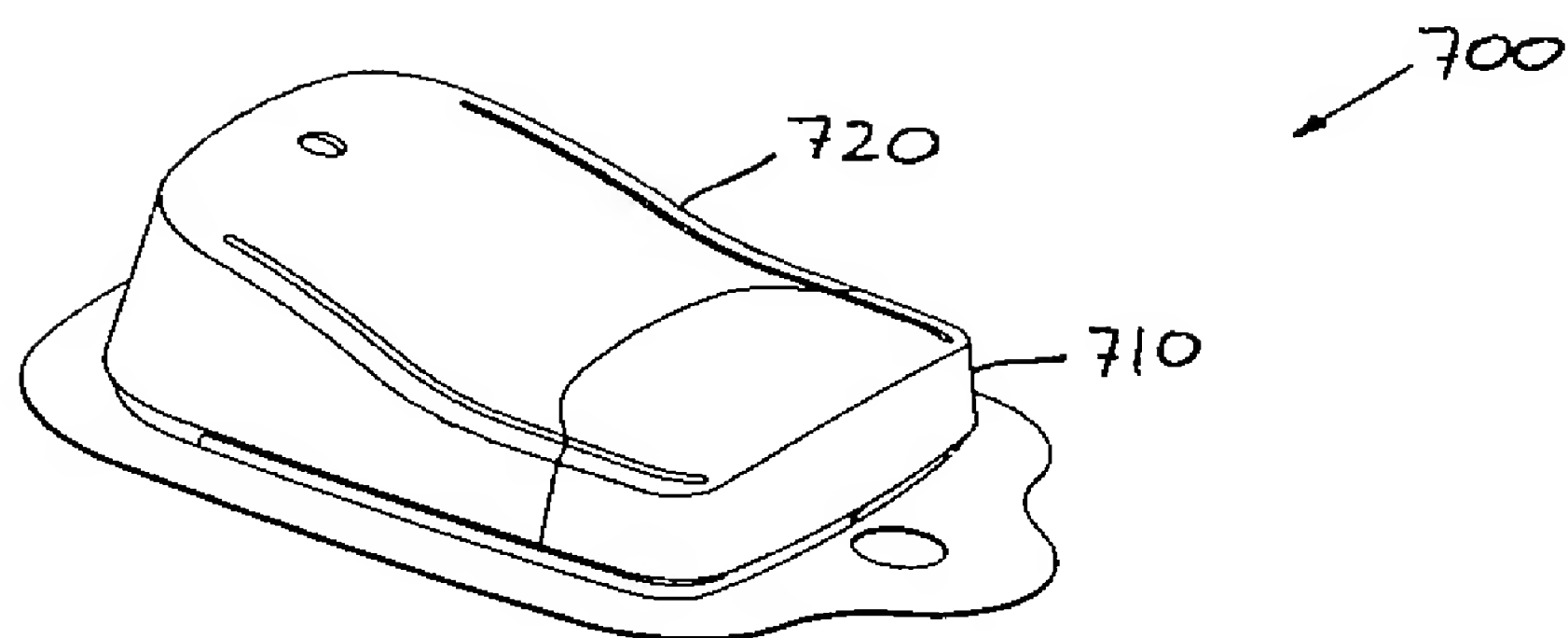


Fig. 16

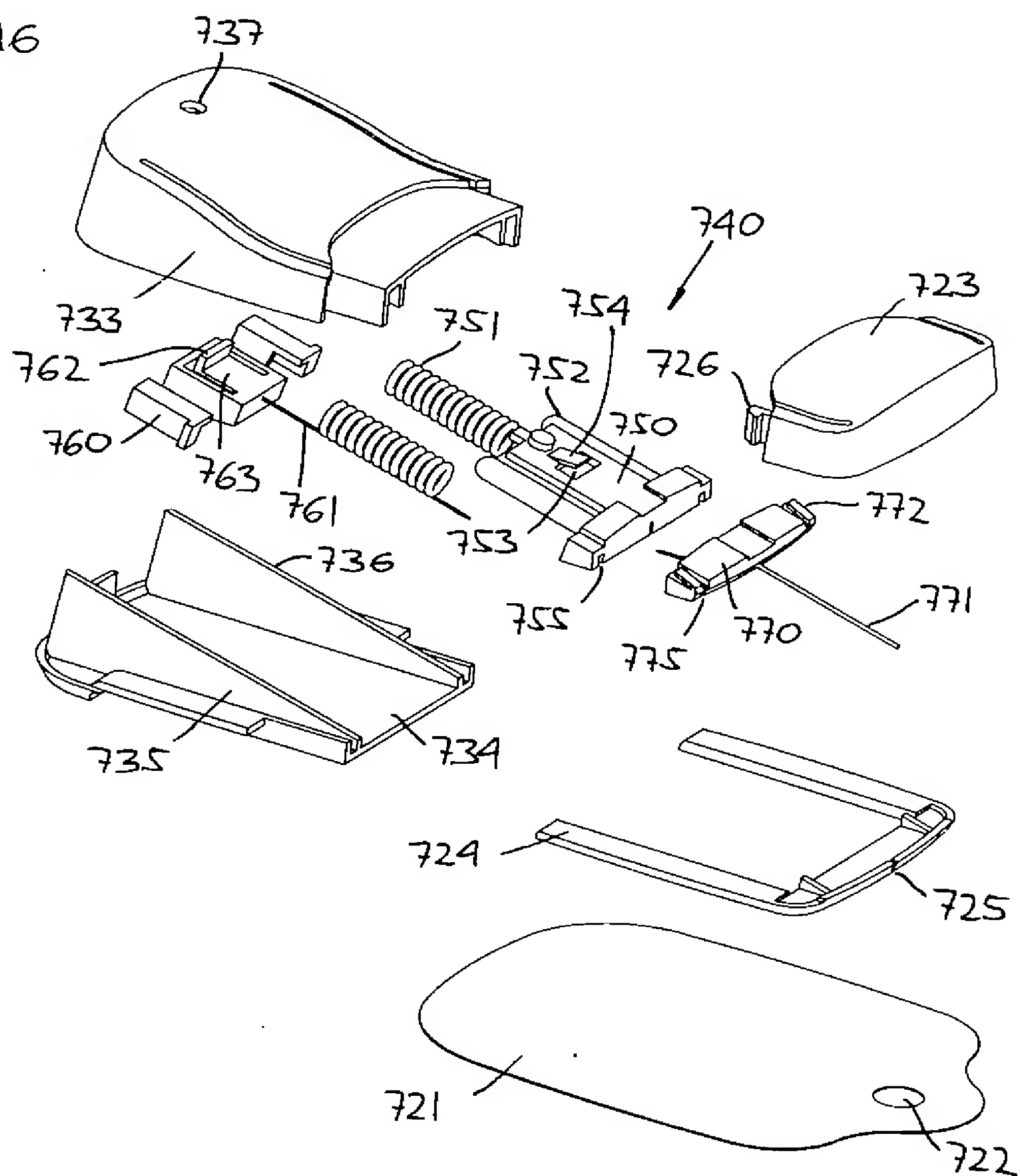


Fig. 17

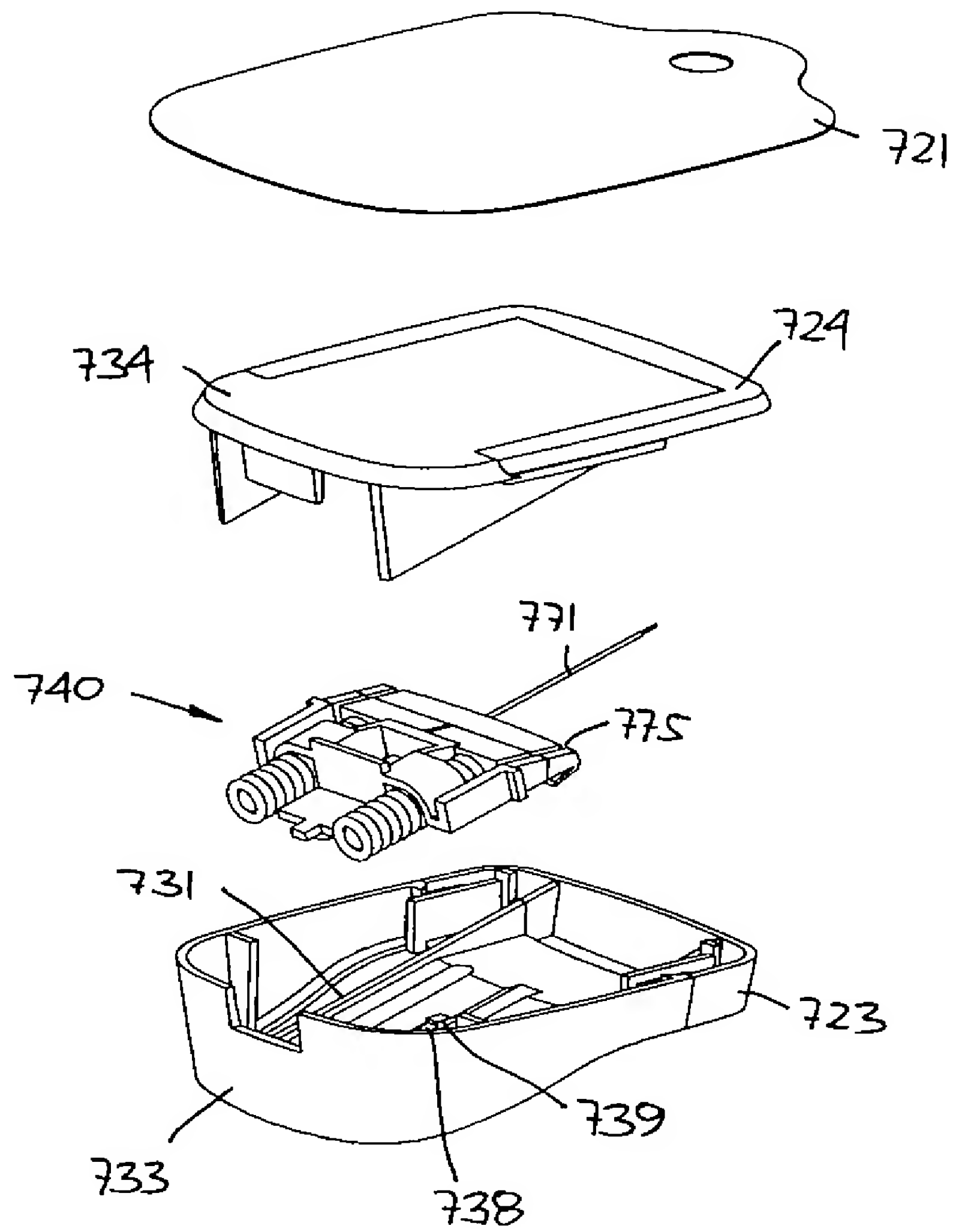


Fig. 27

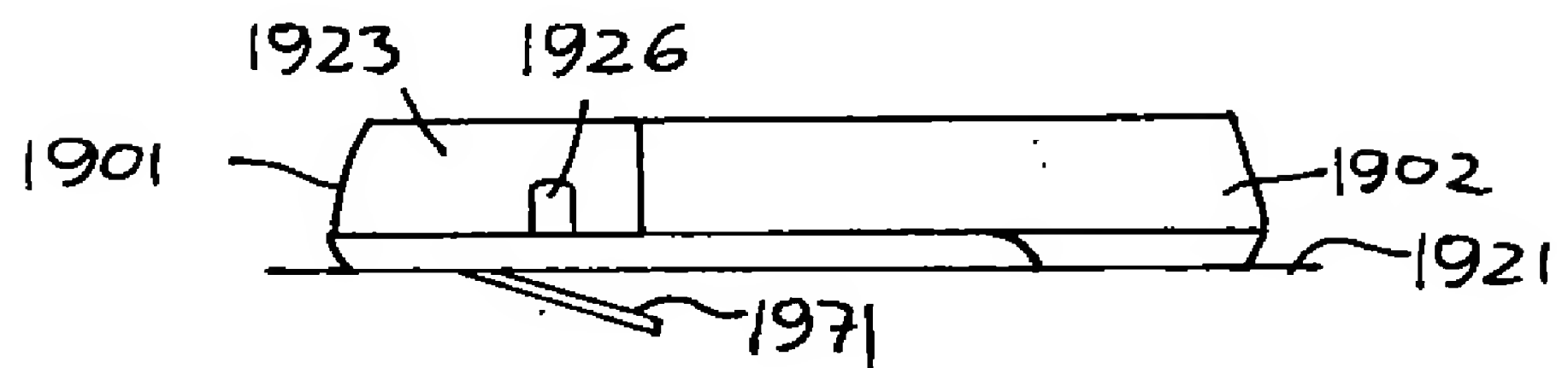


Fig. 18A

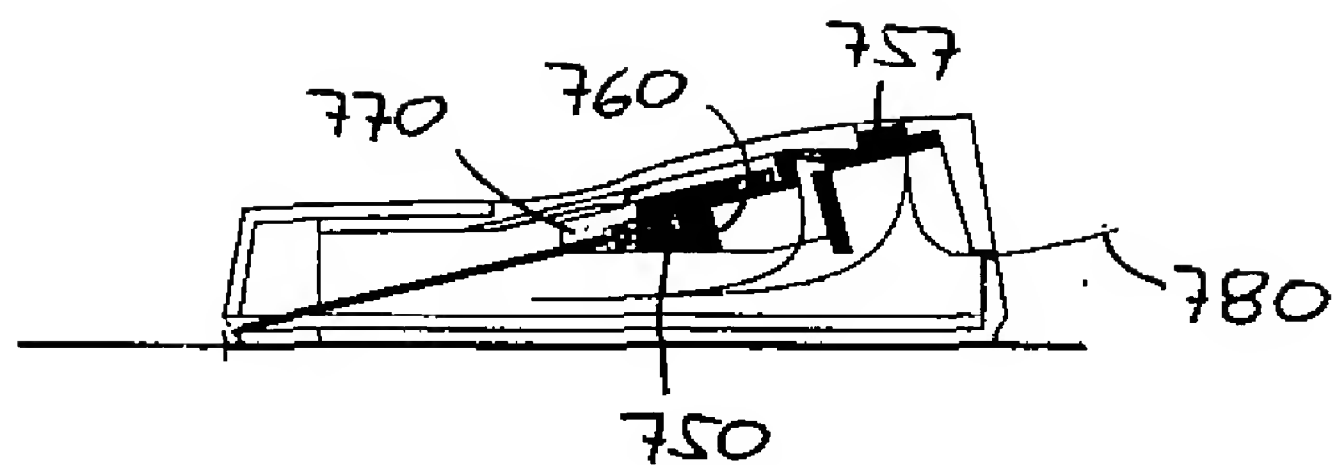


Fig. 18B

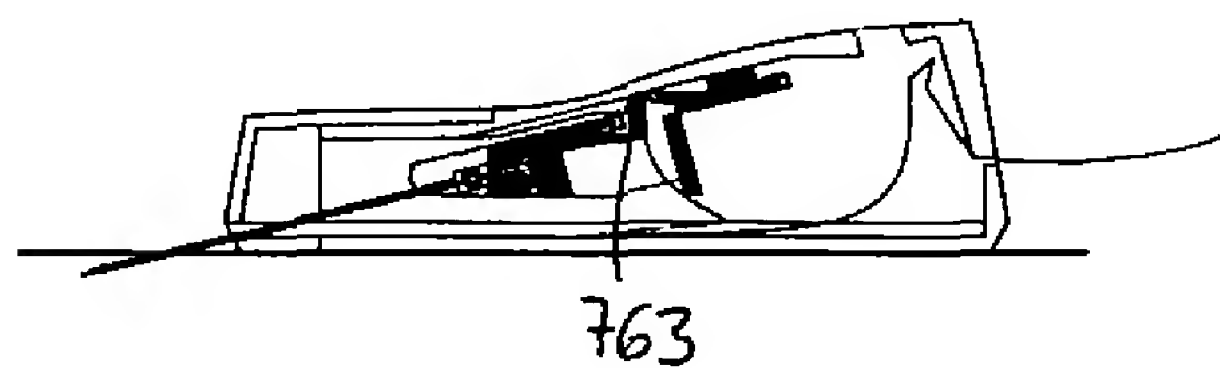


Fig. 18C

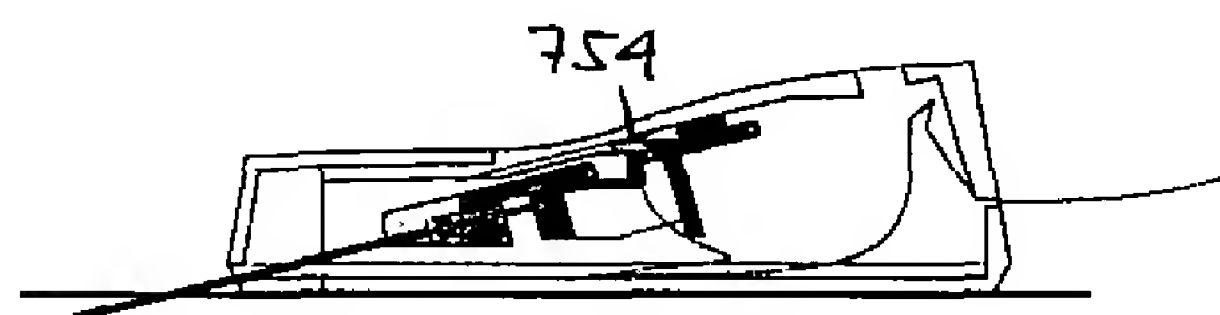


Fig. 18D

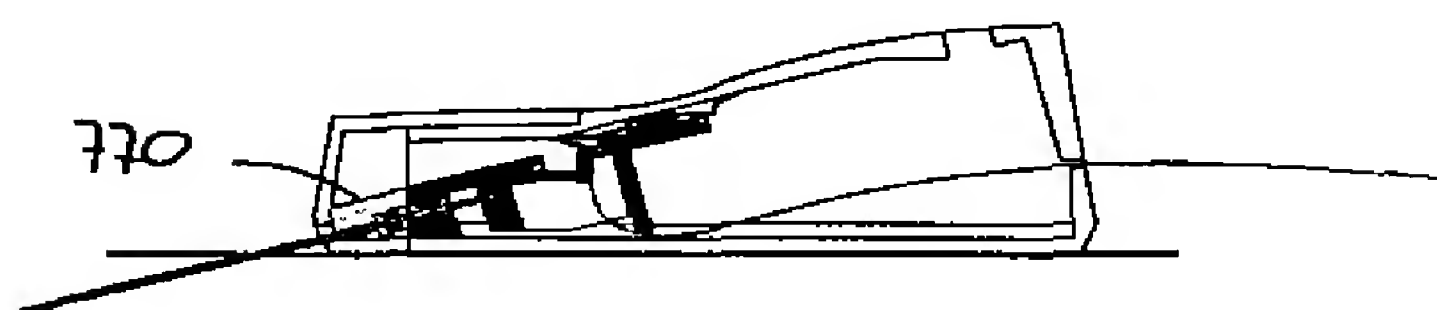


Fig. 18E

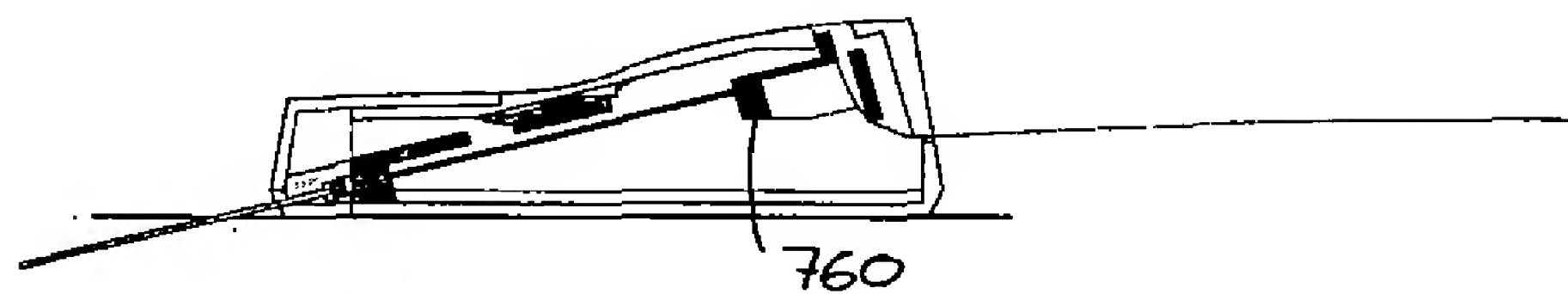


Fig. 18F

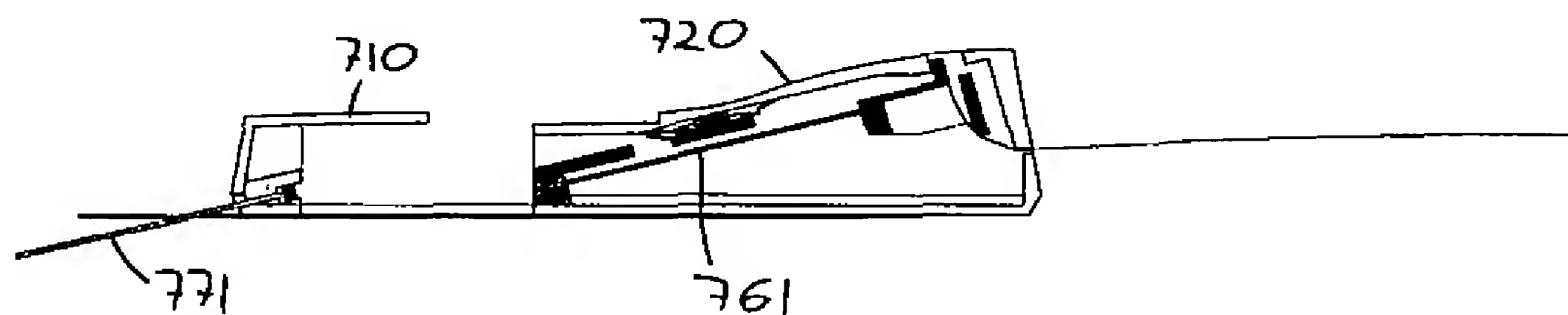


Fig. 19

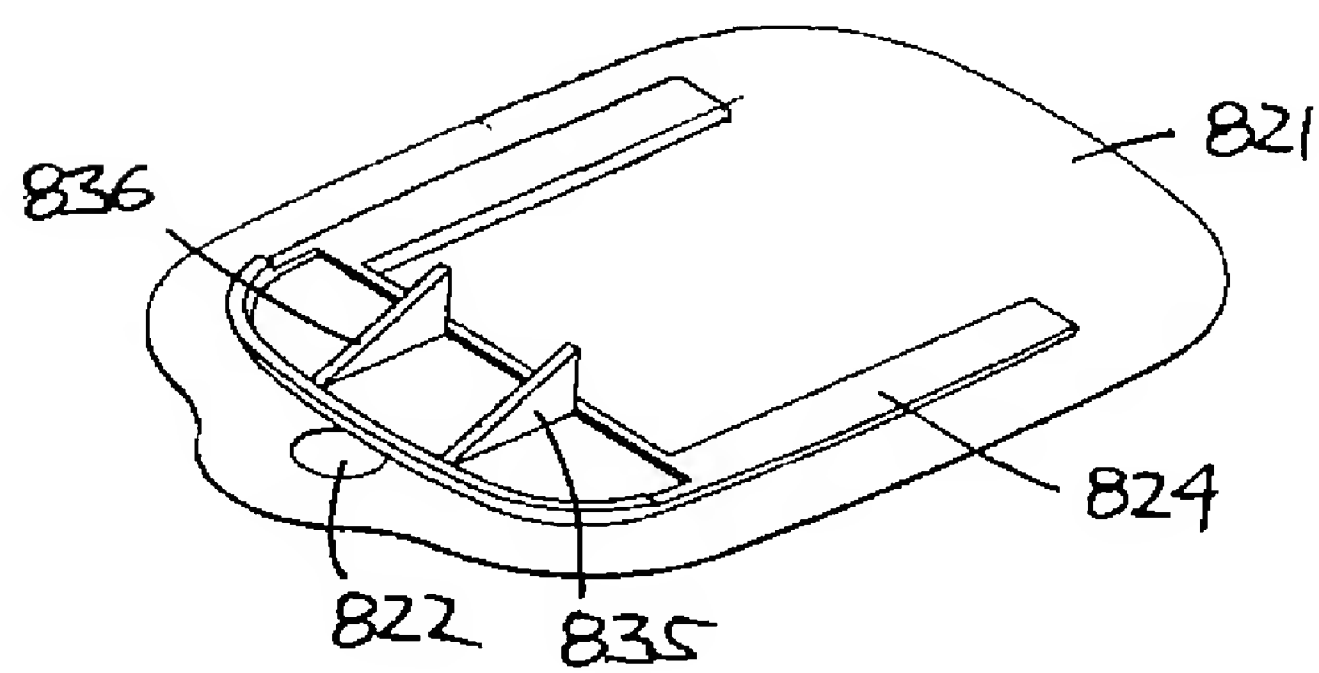
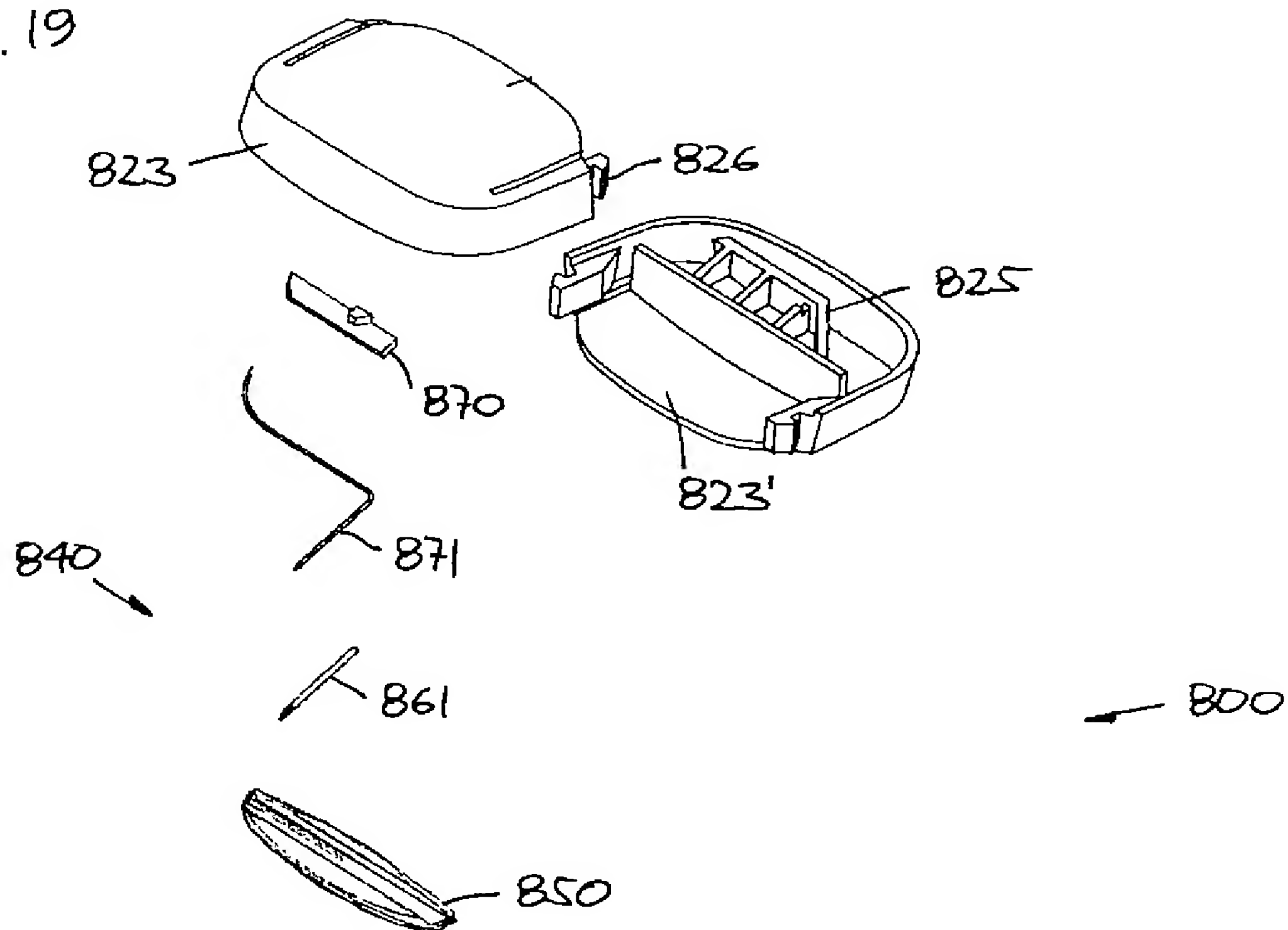


Fig. 20A

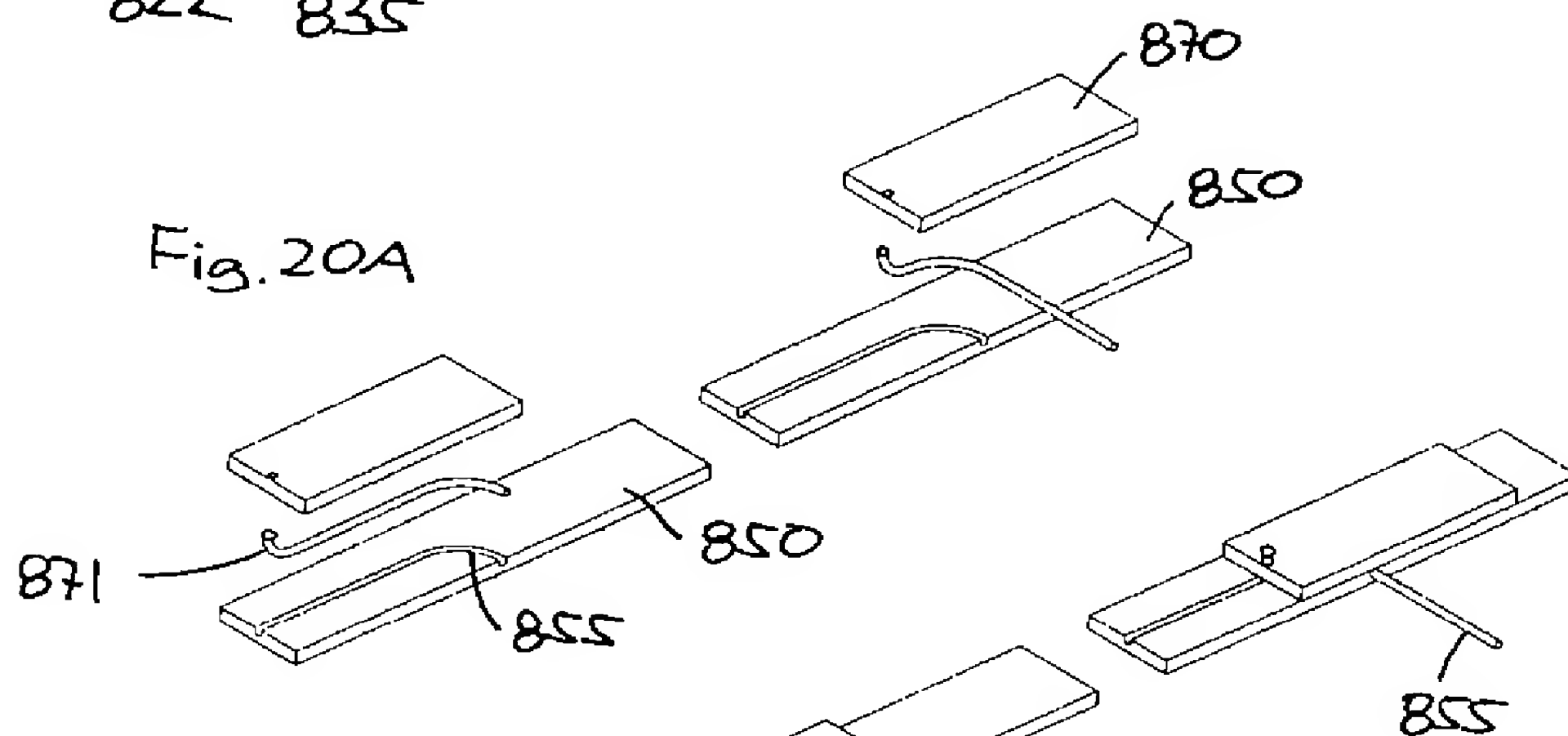


Fig. 20B

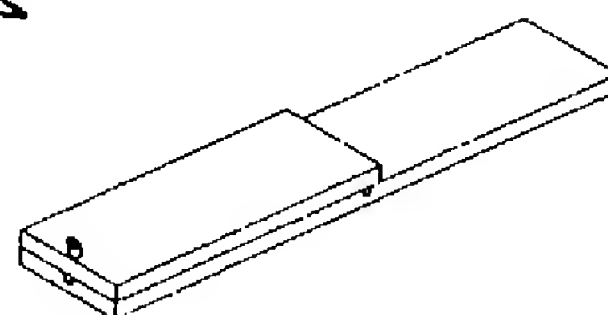


Fig. 21A

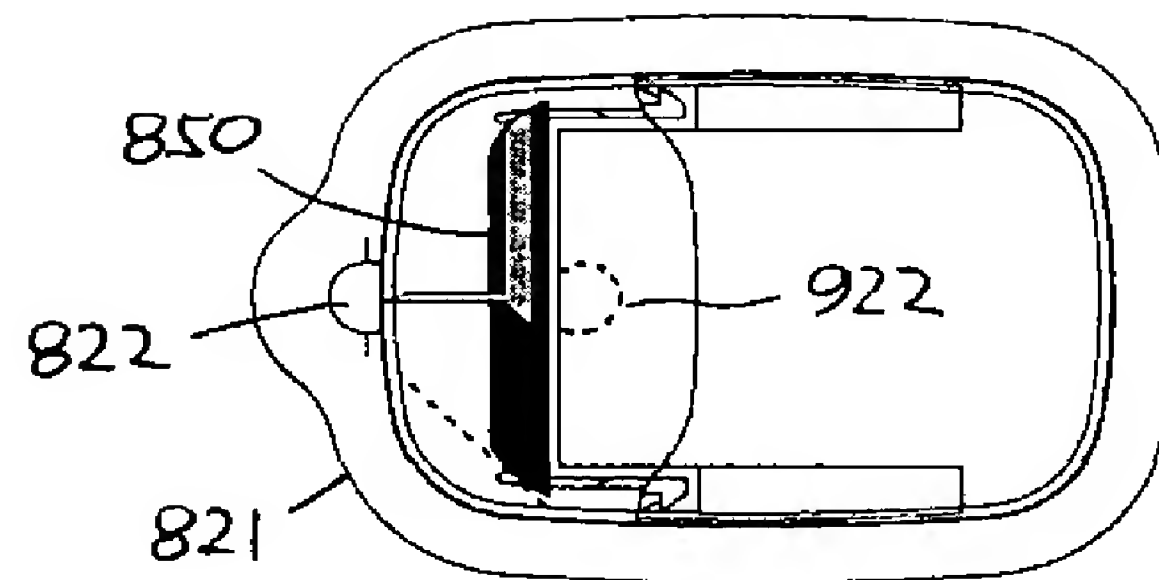


Fig. 21B

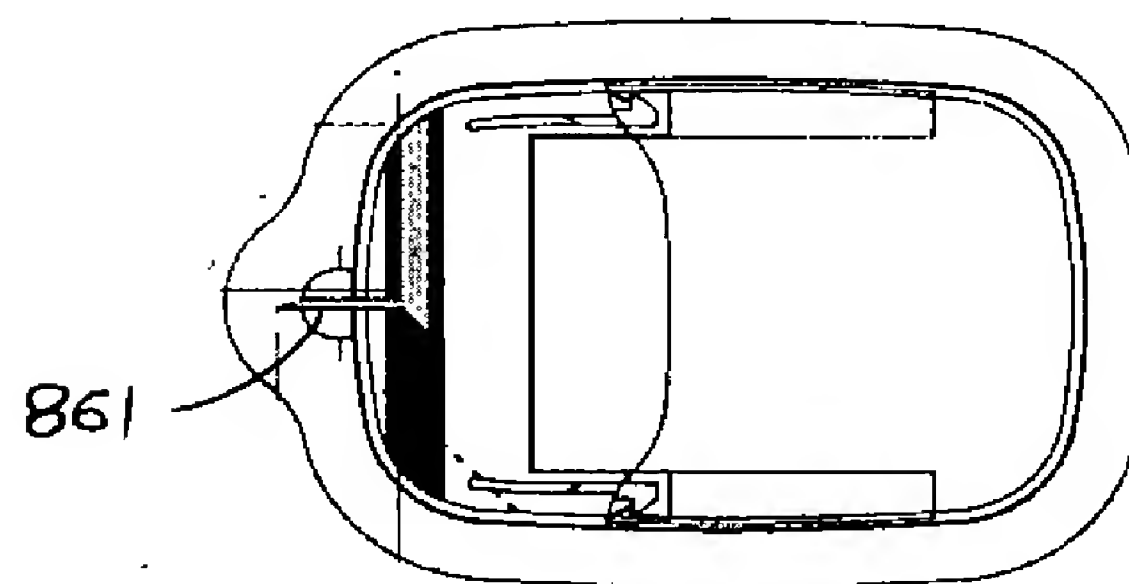


Fig. 21C

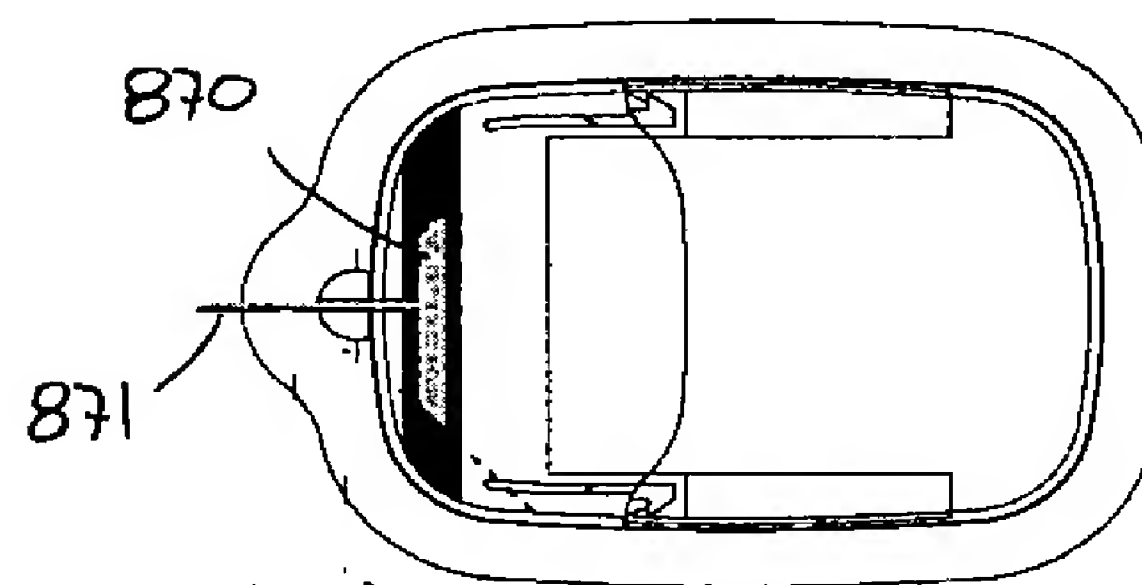


Fig. 21D

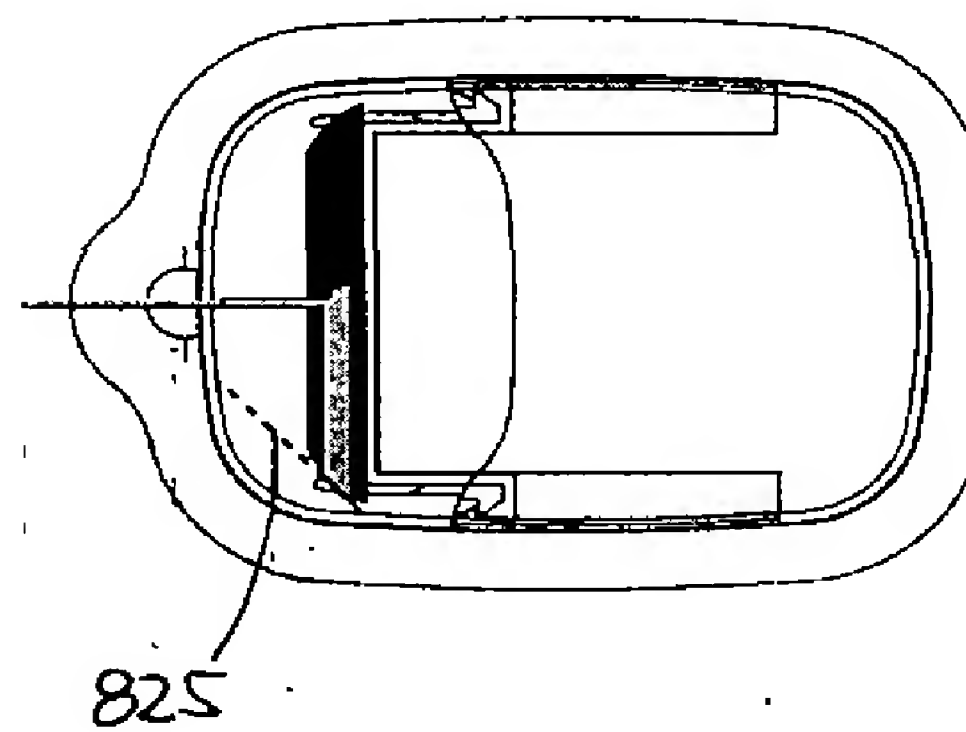


Fig. 22

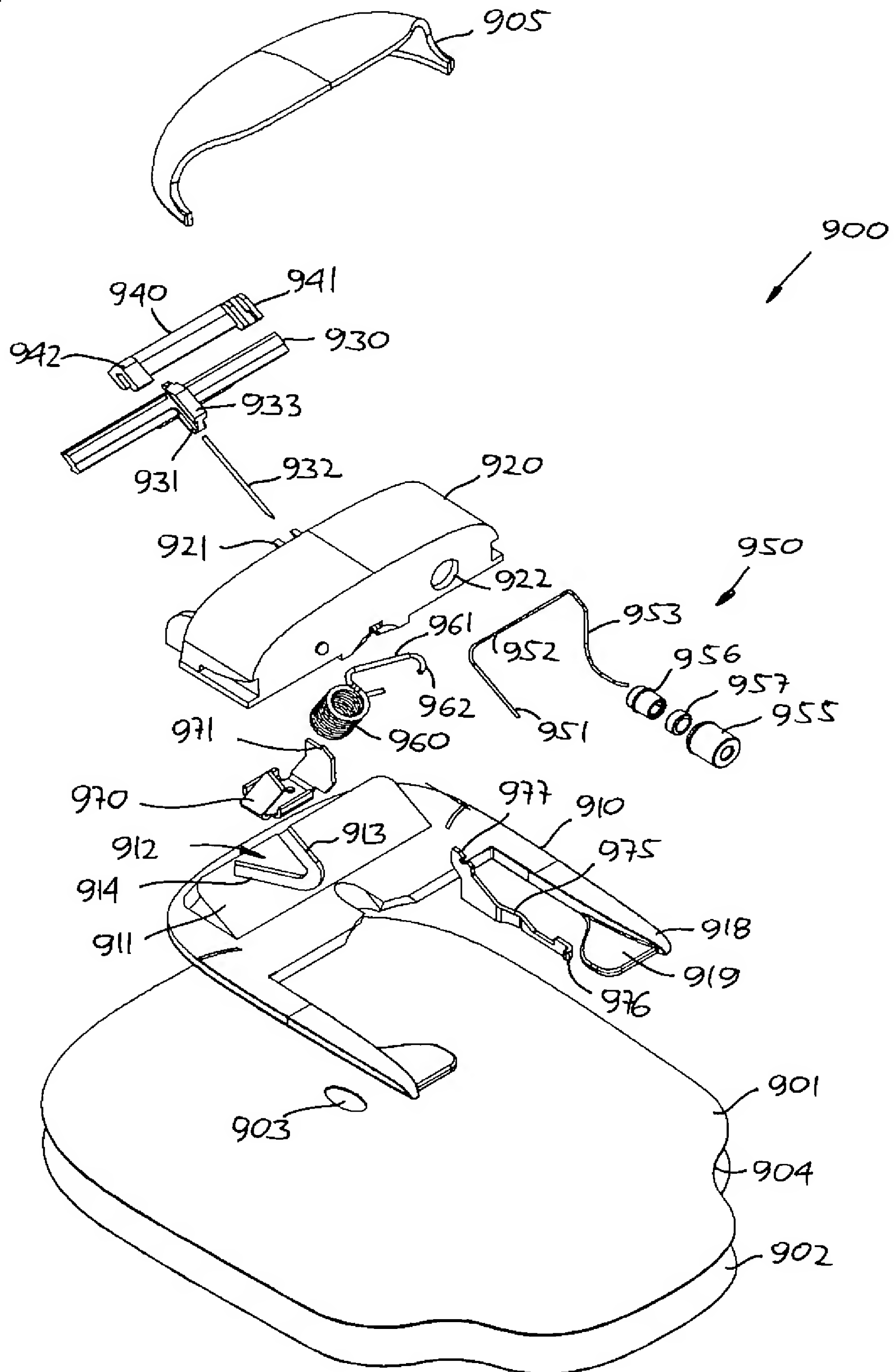


Fig. 23A

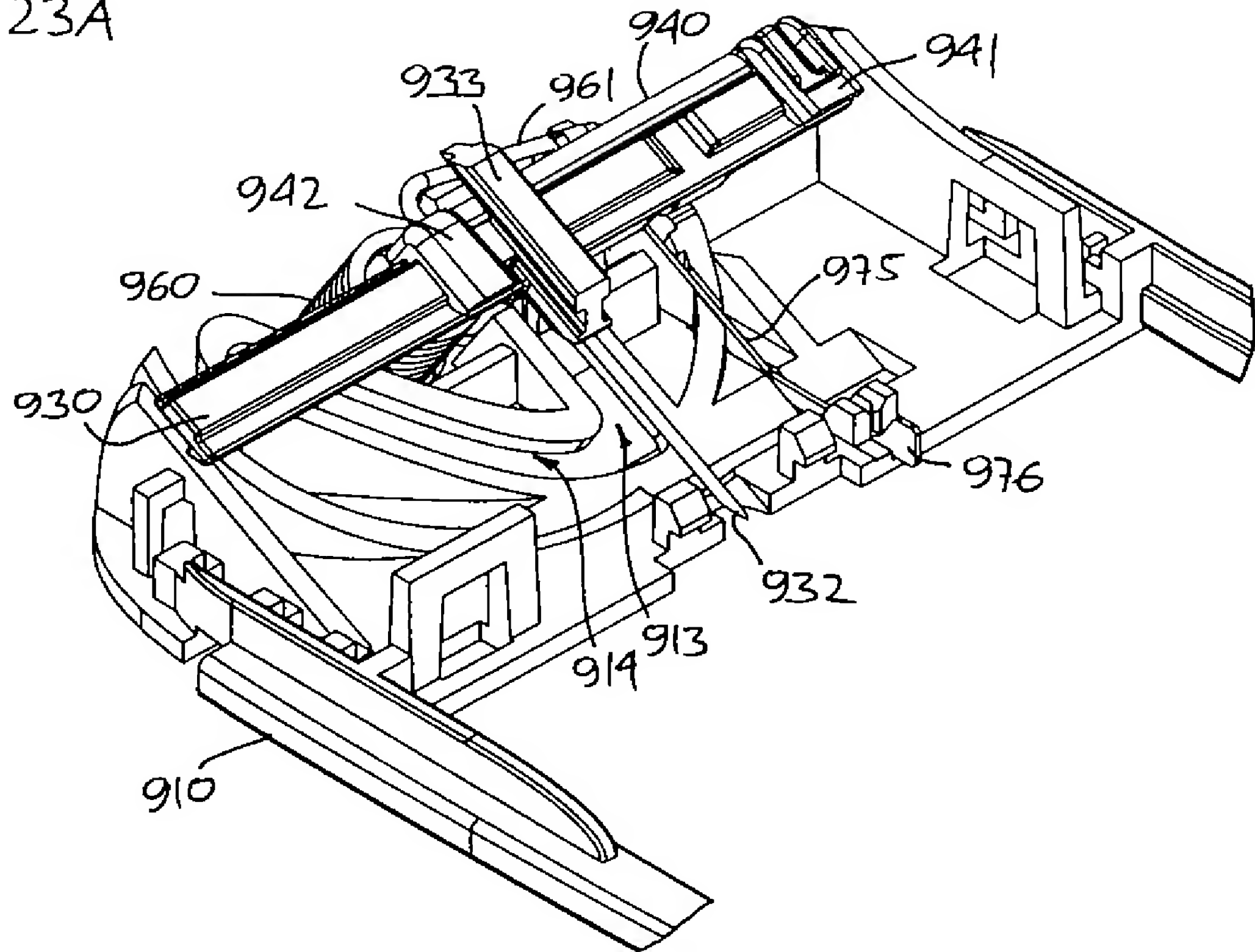


Fig. 23B

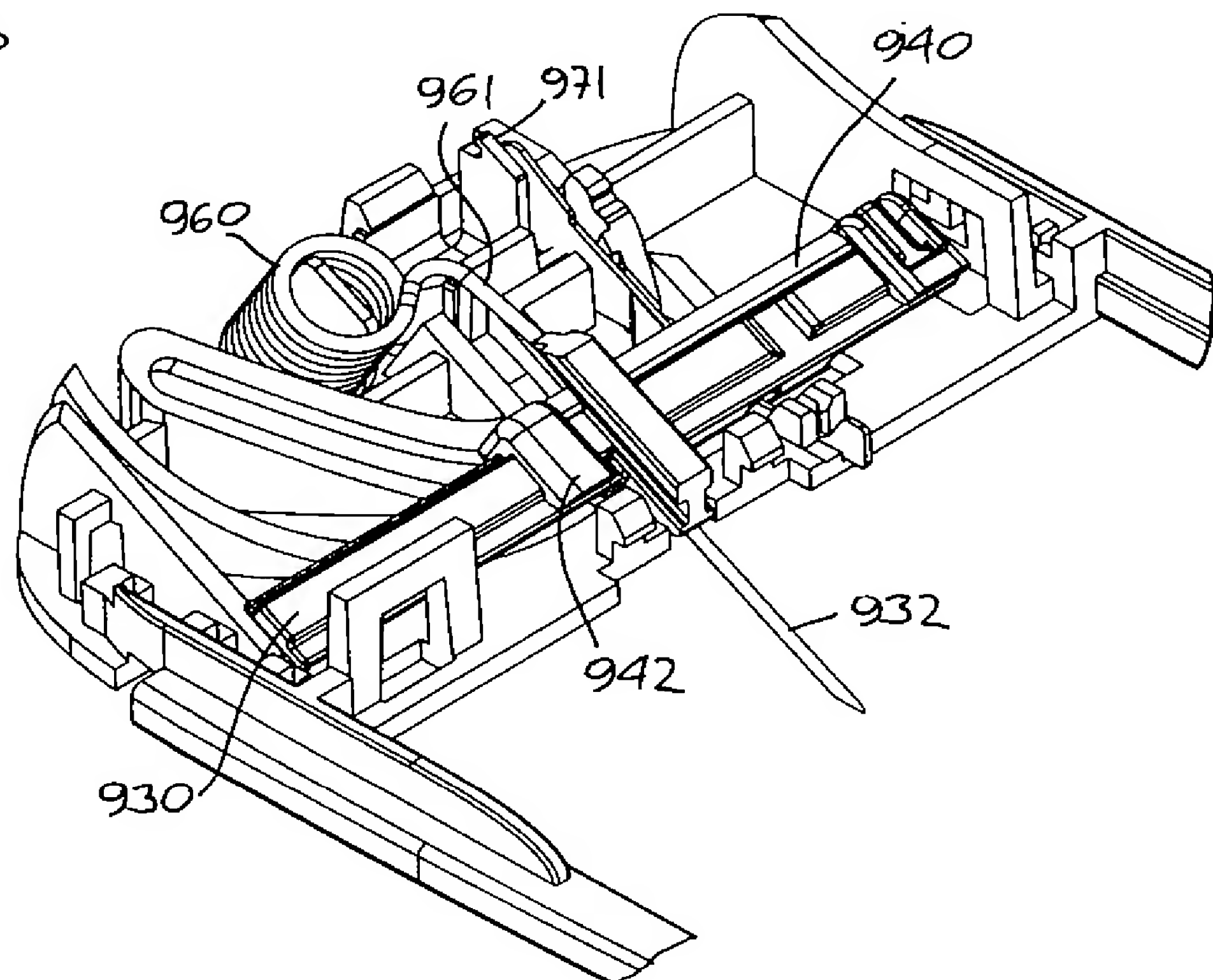


Fig. 23C

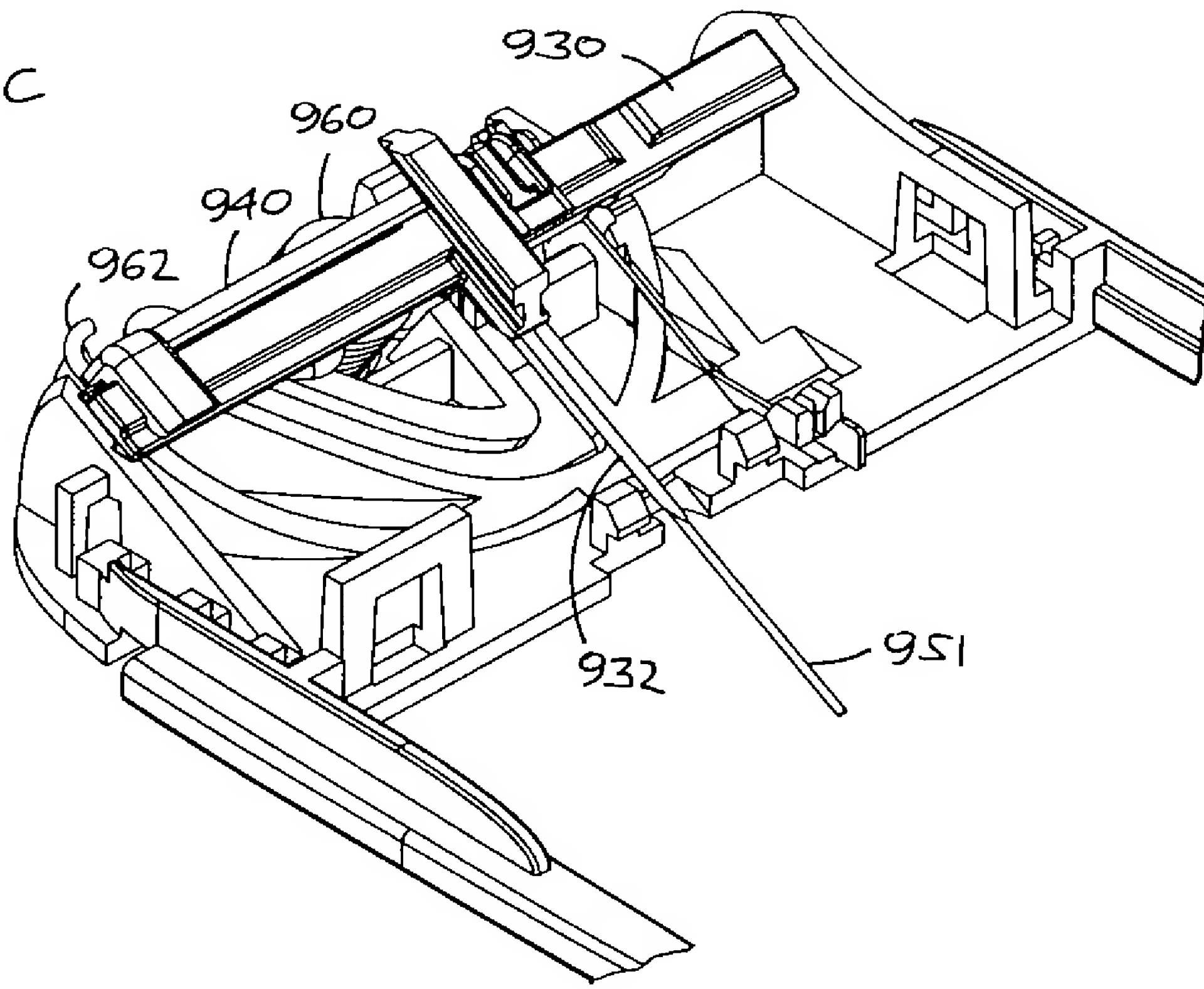


Fig. 23D

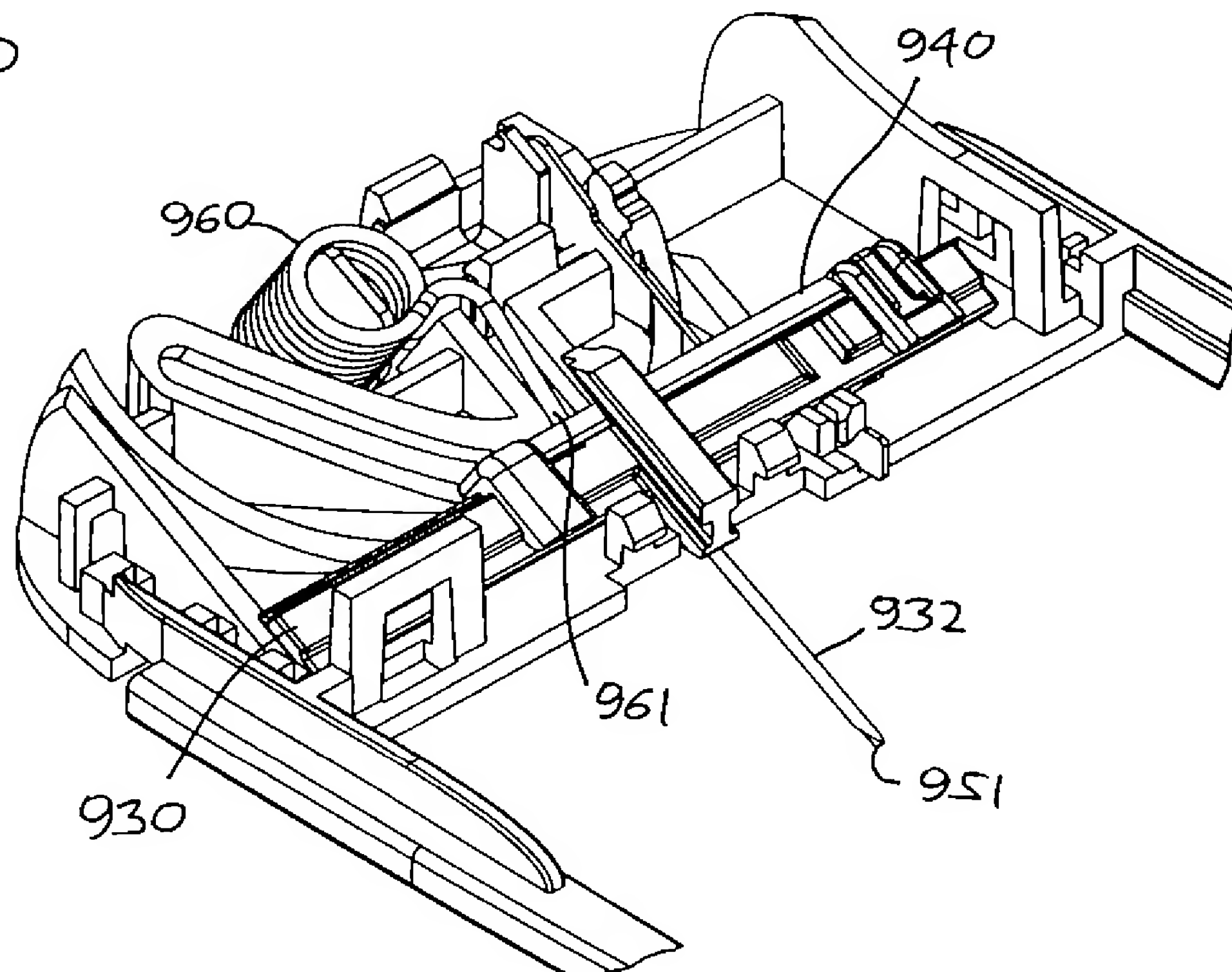


Fig. 24

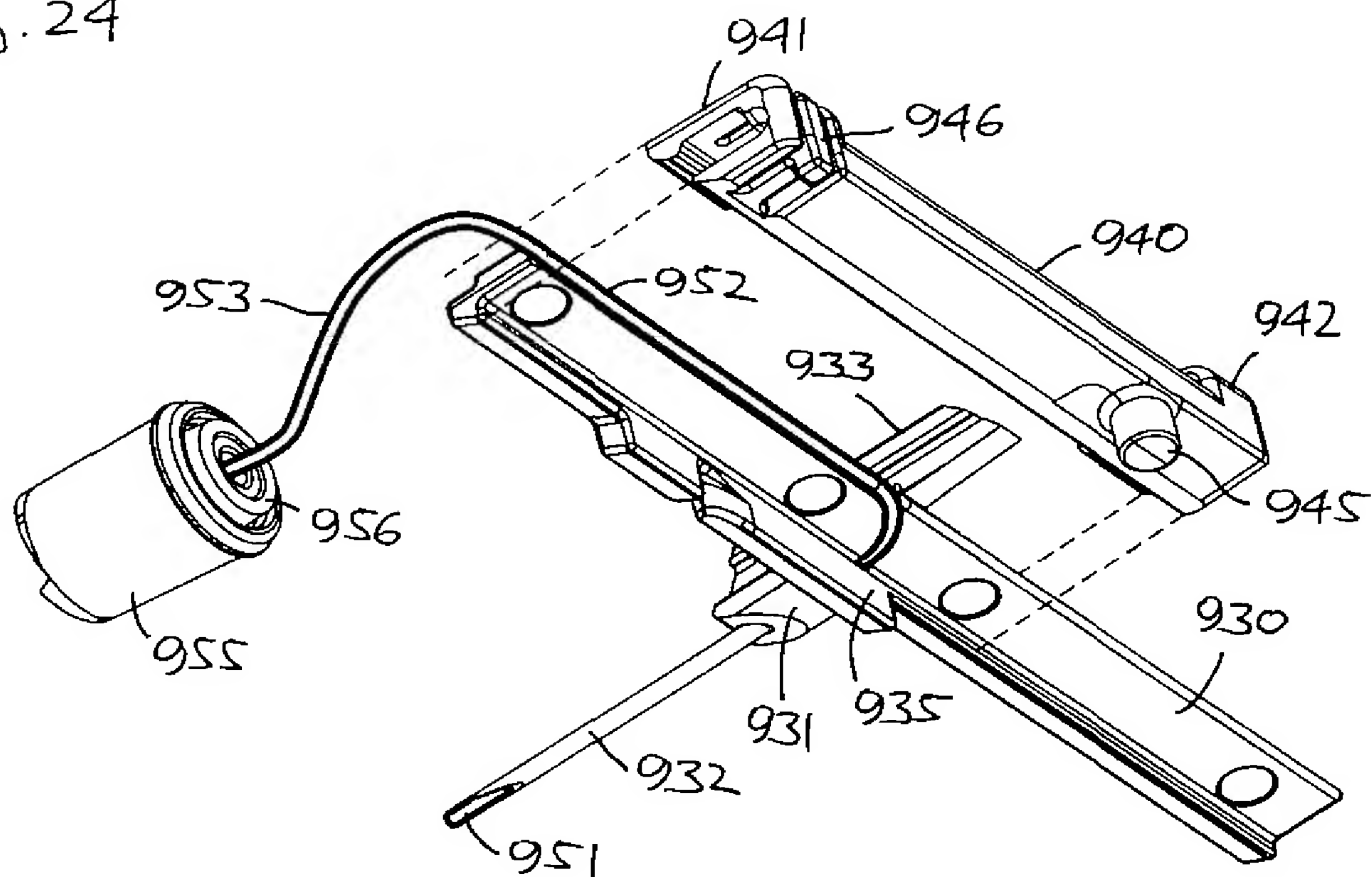


Fig. 25A

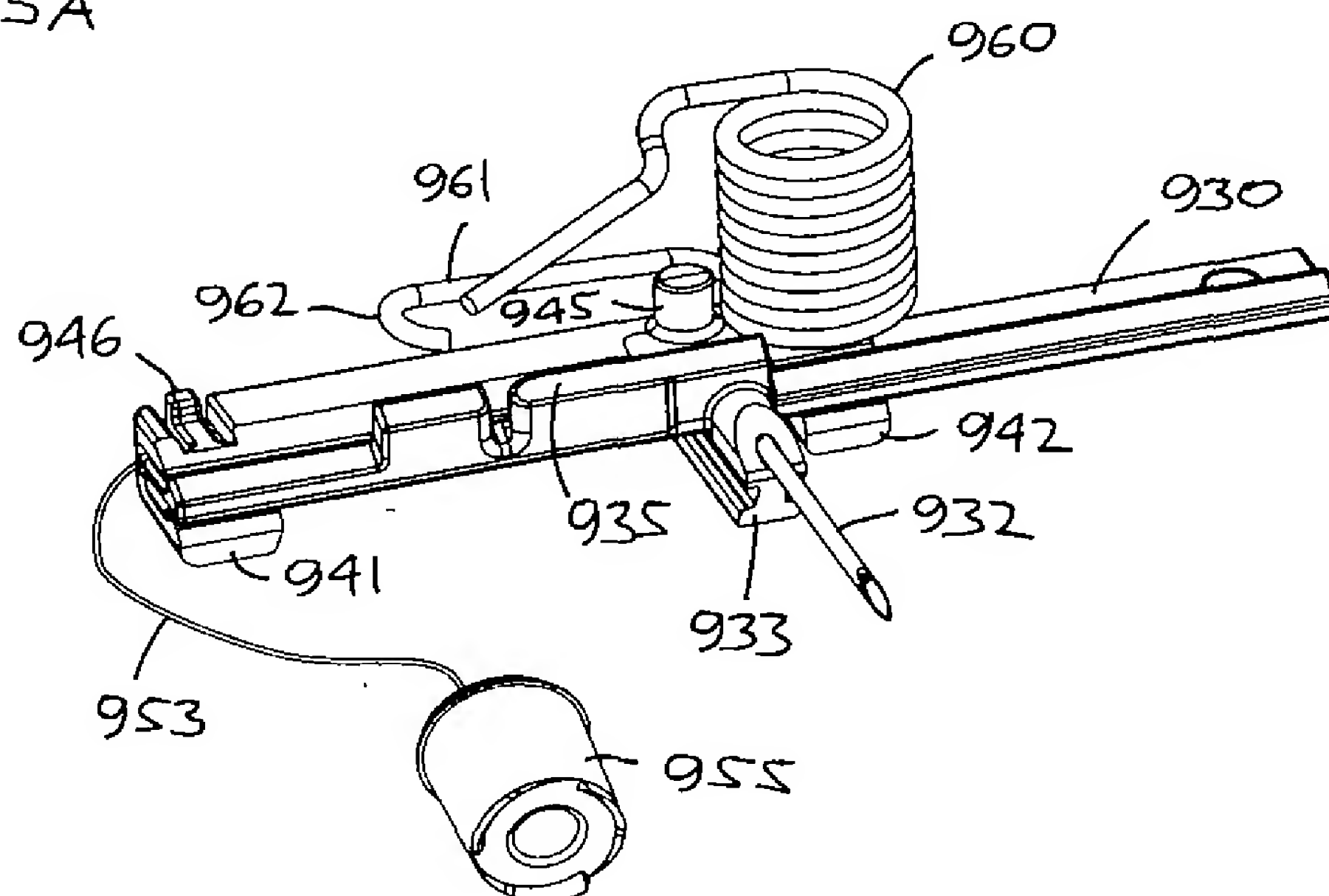


Fig. 25B

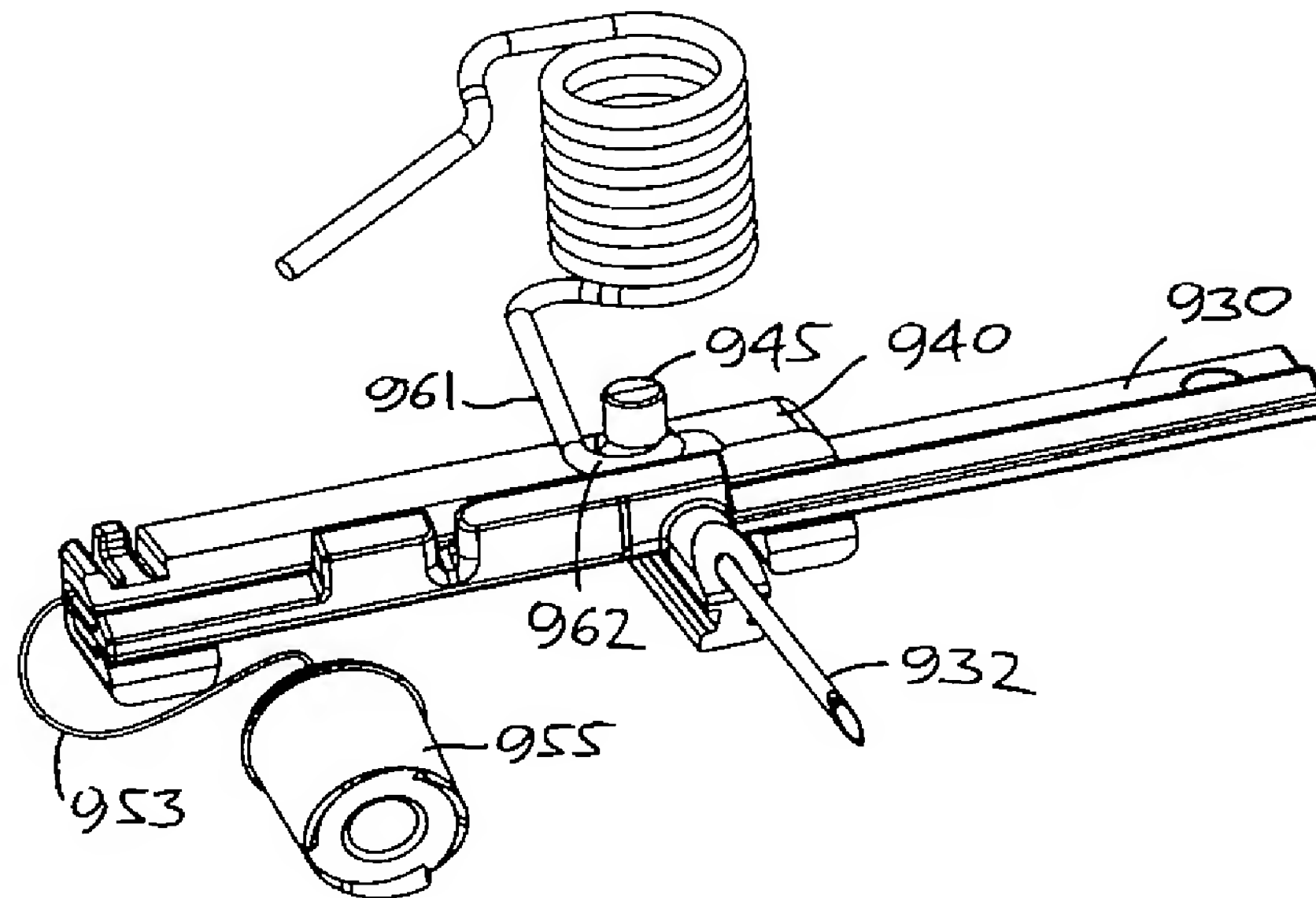


Fig. 25C

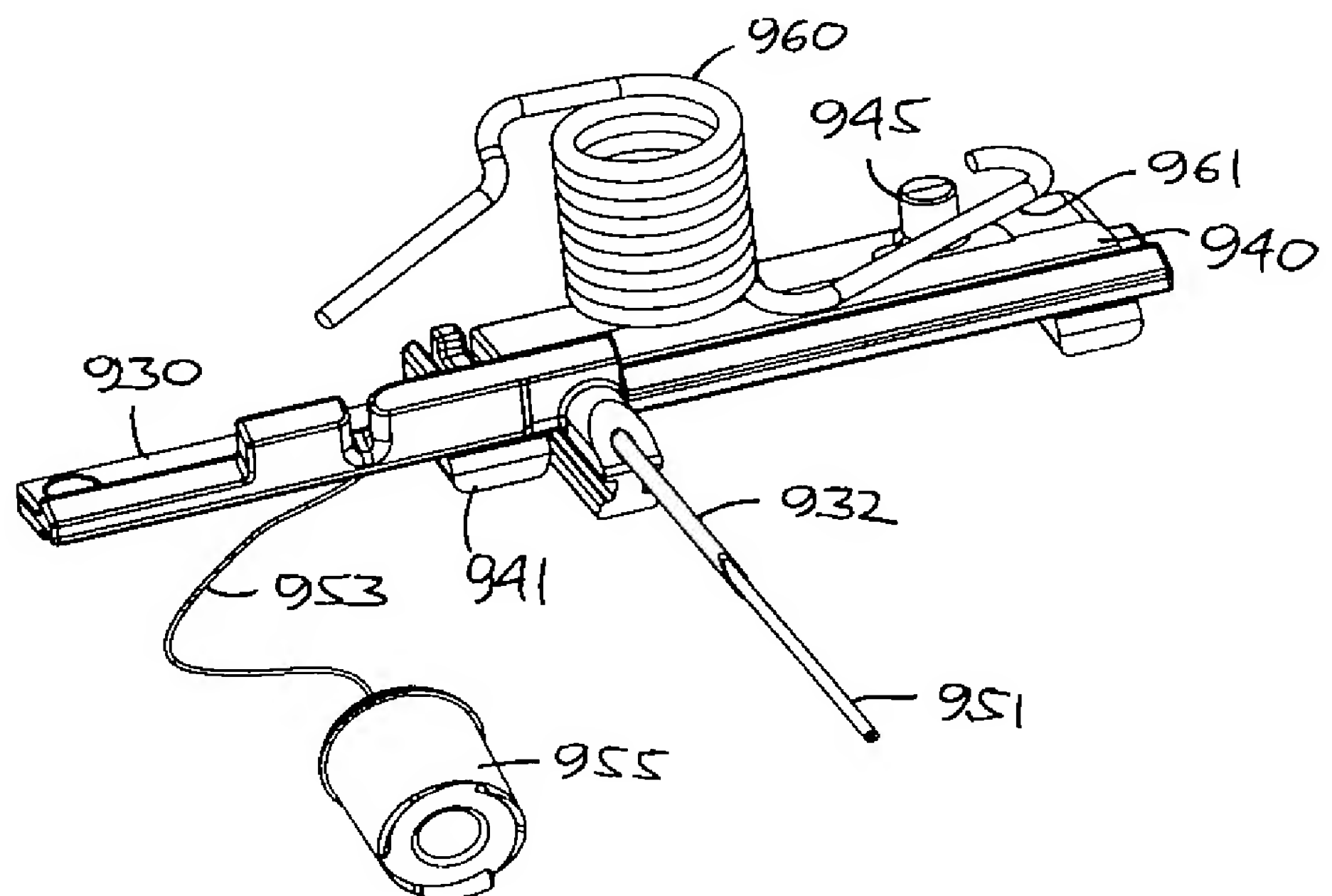


Fig. 26A

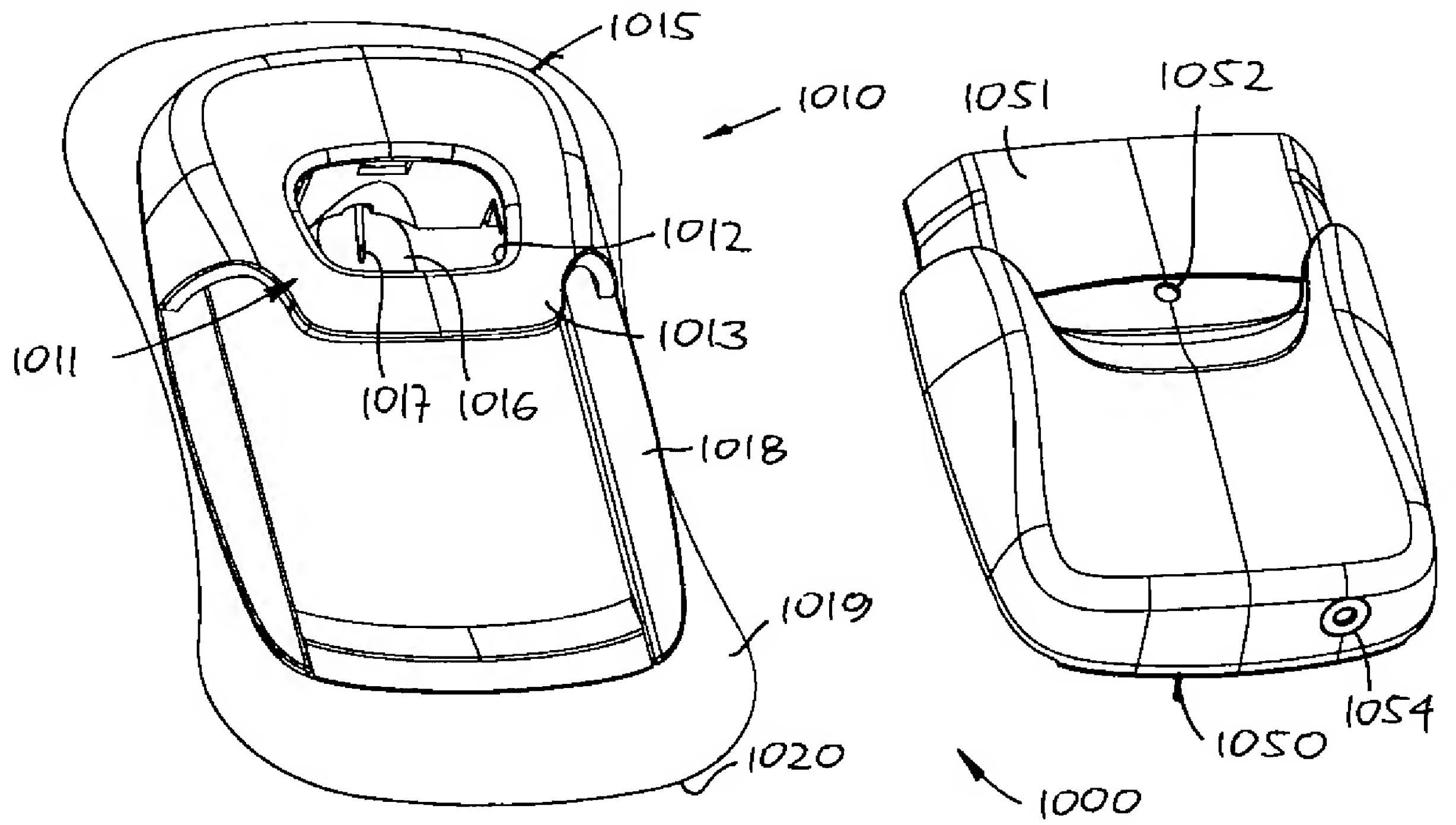
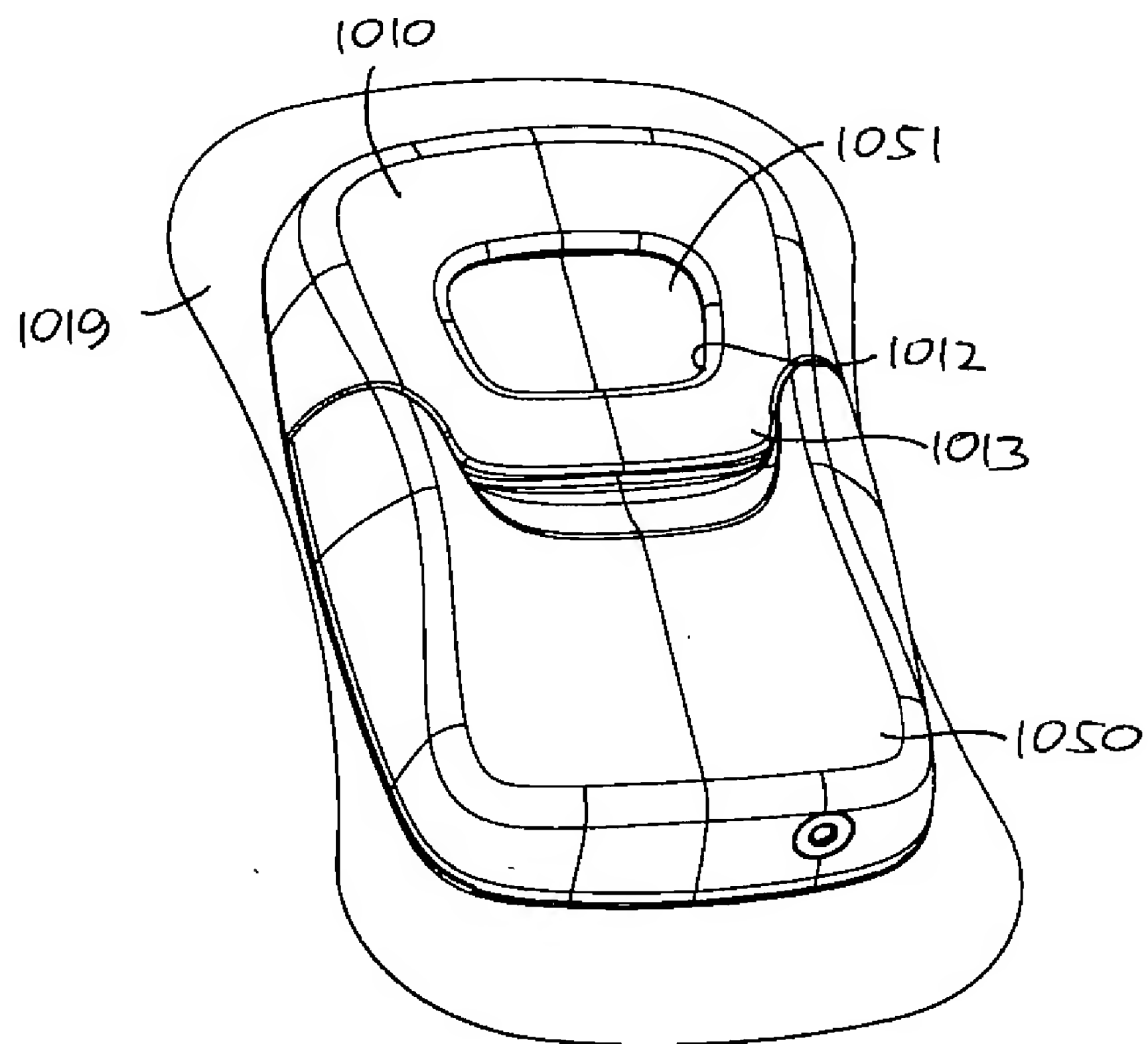


Fig. 26B



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2006/050410

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/158 A61M5/142

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 954 643 A (VANANTWERP ET AL) 21 September 1999 (1999-09-21) figures 1-15 column 3, line 54 - line 66 column 5, line 17 - column 7, line 37 -----	1-6, 10-12, 14
X	WO 03/080169 A (NOVO NORDISK A/S) 2 October 2003 (2003-10-02) figure 9 page 25, line 21 - page 29, line 7 -----	1-6, 10-12, 14
X	US 2003/199823 A1 (BOBROFF RANDA M ET AL) 23 October 2003 (2003-10-23) cited in the application paragraph [0109] - paragraph [0146]; figures 50-60 ----- -/-	1-3, 10-12, 14

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- * & * document member of the same patent family

Date of the actual completion of the international search

16 May 2006

Date of mailing of the international search report

24/05/2006

Name and mailing address of the ISA/

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Authorized officer

Reinbold, S

International application No
PCT/EP2006/050410

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/162521 A1 (BENGTSSON HENRIK) 19 August 2004 (2004-08-19) figures 8-10 paragraph [0089] - paragraph [0094] -----	1,4,5, 10,11
X	US 5 584 813 A (LIVINGSTON ET AL) 17 December 1996 (1996-12-17) figures 1-7 column 4, line 36 - line 65 -----	1,4,5, 10,11
X	US 2003/114797 A1 (VAILLANCOURT VINCENT L ET AL) 19 June 2003 (2003-06-19) figures 36-43 paragraph [0118] - paragraph [0128] -----	1,4-6, 8-11

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 13

The method of claim 13 is carried out within a human body. As stated in the claim (inserting the transcutaneous device into the subject), the method is during a surgical therapy. This method is forming part of a surgical procedure and can therefore not be regarded as an invention which is susceptible of industrial application.

The application does not meet the requirement of Rule 39.1 (iv), because this claim is a method of treatment of the human body.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2006/050410

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 13
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2006/050410

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